77

Supreme Court, U.S.
FILED
DEC 18 2007
OFFICE OF THE CLERK

No. 07- 07-822

IN THE

Supreme Court of the United States

PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, JOSEPH MACKEN, COMMISSIONER LINDA A. WATTERS, AFSCME DISTRICT COUNCIL 47 HEALTH &WELFARE FUND, VICTORIA SCOFIELD, JANET MCGRORTY, RICHARD TIKKURI, WISCONSIN CITIZEN ACTION, UNITED SENIOR ACTION OF INDIANA, NORTH CAROLINA FAIR SHARE,

Petitioners,

v.

ZENECA, INC. and ASTRAZENECA PHARMACEUTICALS, L.P.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

STEVE W. BERMAN
Counsel of Record
CRAIG R. SPIEGEL
HAGENS BERMAN SOBOL SHAPIRO LLP
1301 Fifth Ave., Suite 2900
Seattle, Washington 98101
(206) 623-7292

Attorneys for Petitioners

(Additional Counsel Listed on Inside Cover)

212957

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

BARBARA J. HART
CHRISTOPHER J. MCDONALD
LABATON SUCHAROW LLP
140 Broadway
New York, NY 10005
(212) 907-0700

JAMES R. MALONE, JR.
MICHAEL D. GOTTSCH
DANIEL B. SCOTT
TIMOTHY N. MATHEWS
CHIMICLES & TIKELLIS LLP
361 W. Lancaster Avenue
Haverford, PA 19041
(610) 642-8500

ELLEN MERIWETHER
BRYAN L. CLOBES
CAFFERTY FAUCHER LLP
1717 Arch Street
Suite 3610
Philadelphia, PA 19103
(215) 864-2800

ROBERT S. SCHACHTER
JOSEPH LIPOFSKY
PAUL KLEIDMAN
ZWERLING, SCHACHTER
& ZWERLING, LLP
41 Madison Avenue,
32nd Floor
New York, NY 10010
(212) 223-3900

RONALD S. GOLDSER
ZIMMERMAN REED, PLLP
651 Nicollet Mall, Suite 501
Minneapolis, MN 55402
(612) 341-0400

JEFFREY S. GODDESS
ROSENTHAL MONHAIT &
GODDESS, P.A.
919 Market Street, Suite 1401
Wilmington, DE 19801
(302) 656-4433

JEFFREY L. KODROFF
THEODORE M. LIEVERMAN
SPECTOR, ROSEMAN &
KODROFF, P.C.
1818 Market Street
Suite 2500
Philadelphia, PA 19103
(215) 496-0300

PAMELA S. TIKELLIS
A. ZACHARY NAYLOR
CHIMICLES & TIKELLIS LLP
One Rodney Square
P.O. Box 1035
Wilmington, DE 19899
(302) 656-2500

L. KENDALL SATTERFIELD
RICHARD M. VOLIN
FINKELSTEIN THOMPSON LLP
1050 30th Street, N.W.
Washington, D.C. 20007
(202) 337-8000

RICHARD KIRSCHNER
KIRSCHNER & GARTRELL, P.C.
4910 Massachusetts Ave., NW
Suite 215
Washington, D.C. 20016
(202) 775-0087

JASON J. THOMPSON
CHARFOOS & CHRISTENSEN, P.C.
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

ISSUE PRESENTED FOR REVIEW

Whether 21 U.S.C. § 352(n) and the regulations promulgated thereunder by the Food and Drug Administra-tion preempt all state-law claims for unfair and deceptive marketing of a prescription drug even though Congress stated in the legislation that created § 502(n), P.L. 87-781 § 202, 76 Stat. 793 (Oct. 10, 1962), that "[n]othing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law."

LIST OF PARTIES TO THE PROCEEDINGS

Petitioners Pennsylvania Employees Benefit Trust Fund, Joseph Macken, Commissioner Linda A. Watters, AFSCME District Council 47 Health &Welfare Fund, Vict-oria Scofield, Janet McGrorty, Richard Tikkuri, Wisconsin Citizen Action, United Senior Action of Indiana, and North Carolina Fair Share were plaintiffs in the district court and appellants in the Court of Appeals.

Respondents Zeneca, Inc. and AstraZeneca Pharmaceuticals, L.P. were defendants in the district court and appellees in the Court of Appeals.

CORPORATE DISCLOSURE STATEMENT

None of the petitioners is a corporation.

TABLE OF CONTENTS

	Page
ISSUE PRESENTED FOR REVIEW	i
LIST OF PARTIES TO THE PROCEEDINGS .	ii
CORPORATE DISCLOSURE STATEMENT ..	ii
TABLE OF CONTENTS	iii
TABLE OF APPENDICES	vi
TABLE OF CITED AUTHORITIES	vii
OPINIONS BELOW	1
JURISDICTION	1
CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED	1
STATEMENT OF THE CASE	2
A. Factual Background	4
B. Proceedings Below	12
REASONS FOR GRANTING THE PETITION	17
I. THIS CASE PRESENTS THE IMPORTANT QUESTION OF WHETHER CONGRESS INTENDED	

Contents

Page

21 U.S.C. § 352(n) TO PREEMPT ALL STATE-LAW CLAIMS FOR UNFAIR AND DECEPTIVE MARKETING OF PRESCRIPTION DRUGS 17

A. The Majority's Decision that Congress Intended 21 U.S.C. § 352(n) to Preempt All Claims Under State Law for Deceptive Marketing of Prescription Drugs is Directly At Odds With Congress's Explicit Statement that § 352(n) Preempts Only State Laws that are in "Direct and Positive Conflict" with § 352(n) 17

B. The Majority's Holding that FDA Regulation of Prescription Drug Advertising Preempts All State Claims Conflicts With Decisions by this Court 21

II. THE MAJORITY'S HOLDING THAT 21 U.S.C. § 352(n) AND THE REGULATIONS PROMULGATED THEREUNDER PREEMPT ALL STATE-LAW CLAIMS FOR UNFAIR AND DECEPTIVE MARKETING OF PRESCRIPTION DRUGS IS IN CONFLICT WITH DECISIONS BY

Contents

Page

STATE COURTS OF LAST RESORT AND BY FEDERAL COURTS OF APPEALS 27

CONCLUSION 35

TABLE OF APPENDICES

Page

Appendix A — Opinion Of The United States Court Of Appeals For The Third Circuit Filed August 17, 2007 ..... 1a

Appendix B — Memorandum Opinion Of The United States District Court For The District Of Delaware Dated November 8, 2005 ..... 47a

Appendix C — Order Of The United States Court Of Appeals For The Third Circuit Denying Petition For Rehearing Filed August 17, 200761a

Appendix D — Statutes And Constitutional Provision Involved 63a

TABLE OF CITED AUTHORITIES

Page

CASES

Alpharma, Inc. v. Pennfield Oil Co.,
411 F.3d 934 (8th Cir. 2005) 31

Bates v. Dow Agrosciences LLC,
544 U.S. 431 (2005) 15, 16, 19, 22

In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.,
No. M: 05-1699 CRB, 2006 U.S. Dist. LEXIS 95500 (N.D. Cal. Aug. 18, 2006) 23

Buckman Co. v. Plaintiffs' Legal Comm.,
531 U.S. 341 (2001) 25

Capital Cities Cable, Inc. v. Crisp,
467 U.S. 691 (1984) 24

Carfield v. State,
649 P.2d 865 (Wyo. 1982) 32

City of Gary v. Smith & Wesson Corp.,
801 N.E.2d 1222 (Ind. 2003) 32

Desiano v. Warner-Lambert Co.,
326 F.3d 339 (2d Cir. 2003) 31

Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta,
458 U.S. 141 (1982) 24

Cited Authorities

Page

Ford Motor Co. v. Ins. Comm'r of Penn.,
874 F.2d 926 (3d Cir. 1989) 23

Geier v. American Honda Motor Co.,
529 U.S. 861 (2000) 25

Hill v. Searles Labs,
884 F.2d 1064 (8th Cir. 1989) 31

Hillsborough County v. Automated Med. Labs., Inc.,
471 U.S. 707 (1985) 22, 29

Levine v. Wyeth,
2006 Vt. 107 (2006) 27

Louisiana Pub. Serv. Comm'n v. FCC,
476 U.S. 355 (1986) 24

Mirkin v. Wasserman,
5 Cal. 4th 1082 (1993) 31

Pennsylvania Employees Benefit Trust Fund v. Zeneca Inc.,
499 F.3d 239 (3d Cir. 2007) 1, 2

Perez v. *Wyeth Labs. Inc.*,
161 N.J. 1, 734 A.2d 1245 (1999) 29, 30

S. Blasting Servs., Inc. v. Wilkes County,
288 F.3d 584 (4th Cir. 2002) 28, 33

Cited Authorities

Page

State v. Hernandez-Mercado,
124 Wn.2d 368, 879 P.2d 283 (1994) 32

Thrall v. Wolfe,
503 F.2d 313 (7th Cir. 1974) 32

In re Warfarin Sodium Antitrust Litig.,
391 F.3d 516 (3d Cir. 2004) 31

Wuebker v. Wilbur-Ellis Co.,
418 F.3d 883 (8th Cir. 2005) 23

STATUTES

21 C.F.R. § 202.1 18

7 U.S.C. § 136 21

15 U.S.C. § 52 ..... 2, 18

18 U.S.C. § 848 33

18 U.S.C. § 927 32

21 U.S.C. § 337 1

21 U.S.C. § 352(n) ..... *passim*

108 Cong. Rec. 21046 (1962) 20

Cited Authorities

Page

P.L. 87-781 § 131, 76 Stat. 780 (Oct. 10, 1962) ... 18

P.L. 87-781 § 202, 76 Stat. 793 (Oct. 10, 1962) ...1, 3, 19, 28

S. Rep. No. 87-1744 (1962), reprinted in 1962 U.S.C.C.A.N. 2884, 2904 ..... 14, 20

OPINIONS BELOW

The opinion of the Court of Appeals is reported as *Pennsylvania Employees Benefit Trust Fund v. Zeneca Inc.*, 499 F.3d 239 (3d Cir. 2007) and is reprinted in the Appendix to the Petition ("App.") A. The district court's opinion, which is unreported, is reprinted at App. B.

JURISDICTION

The Court of Appeals entered judgment on August 17, 2007. On September 19, 2007, the Court of Appeals denied a timely petition for rehearing, with three judges (in addition to Judge Cowen, who dissented from the majority decision) voting to grant the petition. App. C. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

The basis for preemption is the Supremacy Clause of the Constitution, which provides in relevant part that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any States to the Contrary notwithstanding." U.S. CONST. Art. VI, cl. 2, reprinted at App. D.

The relevant provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA") are reprinted at App. D. The pertinent statutory provisions are 21 U.S.C. §§ 337 and 352(n). Section 202 of The Drug Amendments Act of 1962, P.L. 87-781, 76 Stat. 780 (Oct. 10, 1962) is reprinted at App. D.

STATEMENT OF THE CASE

This petition presents an issue of exceptional importance – whether Congress clearly and manifestly intended to strip states of their traditional power to protect citizens from deceptive marketing of prescription drugs. The majority opinion denies all judicial recourse under state law to consumers and other payors who lost billions of dollars due to Zeneca's deceptive marketing of Nexium.

Defendants-Respondents AstraZeneca Pharmaceuticals, L.P. and Zeneca Inc. (collectively "Zeneca") make the prescription drugs Prilosec® and Nexium®, the latter of which Zeneca developed as a successor to Prilosec, which went off patent in 2001. Plaintiffs-Appellants ("Plaintiffs") allege that the FDA found that Zeneca's clinical studies do not support the claim that Nexium is superior to Prilosec but that Zeneca nonetheless deceptively marketed Nexium as superior to Prilosec. In a 2-to-1 decision, the Third Circuit affirmed the dismissal of the complaint on preemption grounds. *Pennsylvania Employees Benefit Trust Fund v. Zeneca, Inc.*, 499 F.3d 239 (3d Cir. 2007). The Court of Appeals held that Plaintiffs' claims "would pose an undue obstacle to both Congress's and the FDA's objectives in protecting the nation's prescription drug users." *Id.* at 253. The majority held that by "specifically excluding advertisements covered by 21 U.S.C. § 352(n) and the regulations promulgated thereunder from the scope of 15 U.S.C. § 52, Congress signaled its intent to give the FDA exclusive authority to regulate prescription drug advertising." *Id.*

This Court should review the majority's decision. The holding that Congress intended § 352(n) to "protect[] the nation's prescription drug users," *id.*, by foreclosing their ability to seek redress for unfair or deceptive practices is contrary to the 1962 legislation that created § 352(n). That legislation states that

> "[n]othing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law."

P.L. 87-781 § 202, 76 Stat. 793 (Oct. 10, 1962). Yet the majority points to no such "direct and positive conflict" that requires preemption of all claims under state consumer fraud laws for deceptive marketing of prescription drugs. Indeed, the majority recognizes that Plaintiffs' claims do not conflict with the federal regime: "To the extent that the complaint alleges that Zeneca marketed Nexium as superior to Prilosec, those claims of superiority might be actionable inasmuch as such comparisons are not supported by the labeling and therefore might be false or misleading." 499 F.3d at 246. Moreover, Plaintiffs informed the court that they could allege that "'in negotiations between the FDA and AstraZeneca regarding Nexium labeling, the FDA stated it would not approve any representations by AstraZeneca that Nexium is more effective than Prilosec, and AstraZeneca responded it would not make any such statement.'" *Id.* at 252 (quoting Plaintiffs' proffer). The court held that such allegations of consistency between

Plaintiffs' claims and the FDA's review of Nexium "will not overcome the deficiencies in the complaint because the advertisements are not subject to state consumer fraud law." *Id.* at 252-53.

The conflict in this case is the one created by the majority opinion, which is at odds not only with the intent of Congress to preempt only those state-law claims that are in direct and positive conflict with the FDA's regulation of prescription drug advertising but also with decisions of this Court, other Courts of Appeals, the Third Circuit itself, and State courts of last resort, as explained in this Petition.

This Court should review the majority's flawed decision because it eviscerates the traditional role of states to protect their citizens from false marketing of prescription drugs and because of the harsh and far-reaching ramifications of that ruling, which permits pharmaceutical companies to deceptively market their products without fear of recourse from private parties.

A. Factual Background

This is a class action against Zeneca for unfair and deceptive marketing of the brand-name drug Nexium. Supplemental Appendix ("Supp. App.") ¶ 1.[1] Putting Zeneca's misconduct in context requires an understanding of Prilosec, the prescription drug it was designed to replace. Prilosec is a proton-pump inhibitor ("PPI"). *Id.* PPIs are thought of as heartburn drugs and

1. References to "¶" are to paragraphs of the Consolidated Class Action Complaint contained in the Supplemental Appendix.

are used to treat erosive esophagitis, to maintain healing of erosive esophagitis and to treat symptomatic gastroesophageal reflux disease ("GERD"). Supp. App. ¶ 33. Zeneca had a patent for Prilosec, which by the year 2000 was the most widely prescribed drug in the world, with annual sales in excess of $6 billion. Supp. App. ¶ 32.

The active ingredient in Prilosec, omeprazole, is a racemic mixture containing S- and R-enantiomers. Supp. App. ¶ 38. Enantiomers are molecules that have two non-superimposable mirror image forms, *i.e.*, a right and a left hand version. *Id.* Racemic mixtures, such as omeprazole, contain equal proportions of the two enantiomers. *Id.* Thus, 20 milligrams (mg) of Prilosec comprises 10 mg of the R-enantiomer and 10 mg of the S-enantiomer. *Id.* In humans, the S-enantiomer of omeprazole is more active than the R-enantiomer. Supp. App. ¶ 39.

The United States patent for Prilosec was set to expire in 2001. Supp. App. ¶ 40. With the looming loss of patent protection, Zeneca faced the prospect of competition from generic competitors waiting to market omeprazole. Prilosec was the best selling drug in the world, with sales of $5.9 billion in 2000, which comprised 39% of Zeneca's revenues. Supp. App. ¶ 41.

Faced with the catastrophic loss of sales from its flagship drug, Zeneca plotted a strategy to replace Prilosec. Supp. App. ¶ 45. The centerpiece of that strategy became the marketing of a new drug, Nexium. *Id.* Nexium is simply the S enantiomer of omeprazole. *Id.* In other words, Nexium is Prilosec without the less active Renantiomer. *Id.* Zeneca developed a plan to

launch Nexium and promote it as an improvement over Prilosec to migrate the Prilosec business over to Nexium and to build brand loyalty for Nexium before Prilosec's patent expired and Prilosec became subject to generic competition. Supp. App. ¶ 47.

To gain regulatory approval for Nexium, Zeneca needed only to demonstrate in clinical trials submitted to the FDA that Nexium was more effective than a placebo. Supp. App. ¶ 48. But in an attempt to prove that Nexium was superior to Prilosec, seven of the fourteen clinical trials that Zeneca conducted compared Nexium to Prilosec. Supp. App. ¶ 49.

The FDA approved Nexium for the healing of erosive esophagitis, maintenance of healing of erosive esophagitis and treatment of symptomatic GERD. However, it explicitly rejected Zeneca's contention that Nexium was superior to Prilosec. The FDA's review of Zeneca's Nexium studies ("FDA Review")[2] stated that a claim that Nexium was superior to Prilosec for healing erosive esophagitis is "NOT SUPPORTED." Supp. App. ¶ 53. With respect to three "supportive trials" submitted by Zeneca, the FDA Review stated that "[a]ll three studies failed to demonstrate superiority of [Nexium] over [20 mg of Prilosec]." Supp. App. ¶ 61. Nor did the FDA Review find support for a superiority claim for treating symptomatic GERD. Supp. App. ¶ 67 ("claims of superiority [of Nexium] to [Prilosec] are – once again – not supported. Neither H40 [Nexium 40 mg] nor H20

---

2. Stephen G. Hundley, *FDA Pharmacology/Toxicology Review and Evaluation*, Nexium NDA 21-154, 1-2 (Oct. 31, 2000) (*see* Supp. App. ¶ 49 n.9).

[Nexium 20 mg] could be differentiated from O20 [Prilosec 20 mg]).

A medical review conducted by the FDA confirmed there was no scientific support for a claim of Nexium's superiority over Prilosec.[3] First, the Medical Review found that the studies demonstrated no superiority of Nexium for healing erosive esophagitis:

> [A] superiority claim of Nexium over omeprazole [Prilosec] is ***not supported*** by either the comparison of H20 [Nexium 20 mg] vs. O20 [Prilosec 20 mg] or the comparison of H40 [Nexium 40 mg] vs. H20 [Nexium 20 mg].

Supp. App. ¶ 65 (emphasis added).

Second, the Zeneca studies to establish Nexium's efficacy in maintaining healing of erosive esophagitis did not compare Nexium to Prilosec and, thus, cannot support a claim that Nexium is superior to Prilosec. Supp. App. ¶ 66.

Third, the Medical Review found that the studies on treatment of symptomatic GERD showed no superiority of Nexium over Prilosec:

> [C]laims of superiority [of Nexium] to omeprazole are – once again – ***not supported***.

---

3. Hugo E. Gallo-Torres, M.D., Ph.D, Medical Team Leader, Medical Review(s), FDA Center for Drug Evaluation and Research, Application Number: 21-153/21-154, September 21, 2000 ("Medical Review"), at 3-6 (*see* Supp. App. ¶ 64 n.14).

> Neither H40 [Nexium 40 mg] nor H20 [Nexium 20 mg] could be differentiated from O20 [Prilosec 20 mg].

Supp. App. ¶ 67 (emphasis added).

The "SUMMARY OF BENEFITS VS RISKS" section of the FDA's Medical Review stated:

> It is important to point out that in order to determine whether one compound is superior to another, these drugs need to be tested at comparable amounts: H20 [Nexium 20 mg] vs. O 20 [Prilosec 20 mg]; H40 [Nexium 40 mg] vs. O 40 [Prilosec 40 mg]. The sponsor's comparisons of H 40 to O 20 do not yield valid conclusions about the superiority of H [Nexium] over O [Prilosec], although these comparisons are adequate to demonstrate that [Nexium] is active in the assessed indications. ***Therefore the sponsors conclusions that [Nexium] has been shown to provide a significant clinical advance over [Prilosec] in the first-line treatment of patients with acid-related disorders is not supported by data.***

Supp. App. ¶ 68 (emphasis added). The FDA concluded it would not allow Zeneca to claim that Nexium demonstrated any advantage to Prilosec:

> In addition, it is recommended not to allow the sponsor to claim that [Nexium] has any significant clinical advantage over [Prilosec]

> in the first-line treatment of these acid-related disorders because no data in support of such a claim have been submitted.

Supp. App. ¶ 69.

Zeneca launched a massive promotional campaign aimed at doctors, which was intended to and did create the impression that Nexium, the "new purple pill," was an improvement over Prilosec. Zeneca flew its entire sales force of 6,000 to Hawaii, where they spent an intensive training session on how to convince physicians to prescribe Nexium. Supp. App. ¶ 87. Zeneca trained the sales force to push Nexium as more effective than Prilosec even if doctors were resistant to using Nexium or were happy with Prilosec. *Id.* Teleconferences were held whereby the sales force rehearsed, before Zeneca sales executives, the sales pitch to be made to doctors. *Id.*

After those training sessions, Zeneca's sales force flooded doctors' offices with free samples and claims of Nexium's superiority. Supp. App. ¶ 88. A *Wall Street Journal* article reported this campaign, describing how Zeneca sales representatives promoted Nexium to a doctor, Peter Halper, touting Nexium as superior to Prilosec in "healing rates" and safety. *Id.*

Zeneca's 2000 Annual Report articulated Nexium's central marketing theme:

> ***Nexium is the first PPI to offer significant clinical improvements over*** [***Prilosec***] in terms of acid control and clinical efficacy,

> shown in clinical studies involving over 30,000 patients performed across 20 countries. It is expected to establish a ***new, improved treatment standard for the PPI class.***

Supp. App. ¶ 89 (emphasis added).

Zeneca misleadingly promoted Nexium to doctors as the first PPI to offer significant improvements over Prilosec and its main competitors. Supp. App. ¶ 91. The Zeneca sales force also misleadingly told doctors that Nexium offered more effective acid inhibition than all other PPIs. *Id.* Advertisements directed to doctors suggested that Nexium was more powerful than Prilosec, stating that "we've captured the essence of Prilosec and created a new PPI" and "introducing Nexium the powerful new PPI from the makers of Prilosec." Supp. App. ¶¶ 92, 123, 124 ("We captured the ESSENCE of Prilosec® . . . and created a NEW PPI . . . Introducing NEXIUM™ ... The POWERFUL new PPI from the makers of Prilosec®"). Zeneca made those claims even though the FDA found that Zeneca's clinical trials showed that claims of superiority are "not supported." Supp. App. ¶ 93. In sales pitches to doctors, Zeneca employees also falsely conveyed the message that Nexium was the first PPI to offer improvements over Prilosec and that Nexium was "improved treatment for the PPI class." *Id.* at ¶ 95.

Zeneca built the Nexium campaign around the brand identity already established with Prilosec. Zeneca had long heavily advertised Prilosec as "the purple pill" to relieve heartburn. It then capitalized on that brand identity by marketing Nexium in a way that connected

it to, yet distinguished it from, Prilosec, *e.g.*, as the "new" purple pill, "today's" purple pill, the "healing" purple pill, or by stating that relief is "possible with the purple pill called Nexium." Supp. App. ¶¶ 116, 117. Nexium advertisements targeting physicians and consumers conveyed the false and misleading message that Nexium was a clinical advance over, and a superior drug to Prilosec, which by comparison became ***yesterday's*** purple pill, the ***old*** purple pill.

In 2003, the administrator of the federal Centers for Medicare and Medicaid Services, Tom Scully, told doctors at a convention of the American Medical Association that they should not prescribe Nexium because Prilosec, which had just become available in generic form, cost less and provided the same level of treatment. Supp. App. ¶ 106. Indeed, Mr. Scully scolded doctors, "You should be embarrassed if you prescribed Nexium" because it increased costs without medical benefits. "The fact is, Nexium is Prilosec," Mr. Scully said. "It is the same drug. It is a mirror compound." Aptly describing Zeneca's scheme, Mr. Scully stated that "Nexium is a game that is being played on the people who pay for the drugs making it one of the most successful launches ever of a new medicine." Supp. App. ¶ 106.

Sales of Prilosec plummeted in response to generic competition. Supp. App. ¶ 107. After establishing Nexium's position and capitalizing on brand loyalty, Zeneca raised the price of Nexium while the price of Prilosec dropped. Supp. App. ¶ 108. As of 2005, Nexium sold for more than $4.00 per pill versus $0.67 per pill or less for Prilosec. *Id.* Sales figures reveal the success of

Nexium in replacing Prilosec. Supp. App. ¶ 109. For example, sales of Prilosec in the United States dropped from $3.694 billion in 2001 to $867 million in 2003, while sales of Nexium rose from $580 million in 2001 to $2.477 billion in 2003.

B. Proceedings Below

Plaintiffs allege violations of the Delaware Consumer Fraud Act (6 Del. C. § 2511, *et seq.*) and consumer-protection statutes of 48 states, and assert claims for unjust enrichment and negligent misrepresentation. The district court dismissed the complaint.

The Third Circuit Court of Appeals affirmed the dismissal in a 2-to-1 decision. The majority held that "[b]y specifically excluding advertisements covered by 21 U.S.C. § 352(n) and the regulations promulgated thereunder from the scope of 15 U.S.C. § 52, Congress signaled its intent to give the FDA exclusive authority to regulate prescription drug advertising." 499 F.3d at 253. The majority also stated:

> Implied conflict preemption of state consumer fraud laws is required in this setting because both the FDCA and FDA regulations provide specific requirements for prescription drug advertising. Congress specifically determined that "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The high level of specificity in federal law and regulations with respect to prescription drug

> advertising is irreconcilable with general state laws that purport to govern all types of advertising. *See, e.g.*, 21 U.S.C. § 352(n); 21 C.F.R. § 314.81(b)(3). Accordingly, the plaintiffs' state consumer fraud claims are preempted.

Id. at 251-52. The majority held that state-law claims for deceptive marketing are preempted even if the claims are wholly consistent with FDA regulations and findings:

> [T]he plaintiffs state that they could allege that "in negotiations between the FDA and AstraZeneca regarding Nexium labeling, the FDA stated it would not approve any representations by AstraZeneca that Nexium is more effective than Prilosec, and AstraZeneca responded it would not make any such statement." This will not overcome the deficiencies in the complaint because the advertisements are not subject to state consumers fraud law, as explained in part III.

Id. at 252-53.

In dissent, Judge Cowen explained that the majority opinion rests on a ground never raised by Zeneca (*id.* at 254 n.13) and is contrary to well-established Supreme Court principles. Judge Cowen stated:

> The majority's conclusion that the FDCA and the implementing regulations displace the Delaware Consumer Fraud Act and the consumer protection statutes of the fifty states

> "ignore[s] the teaching of th[e] [Supreme] Court's decisions which enjoin seeking out conflicts between state and federal regulation where none clearly exists." *Huron Portland Cement Co. v. City of Detroit, Mich.*, 362 U.S. 440, 446 (1960). Because the state laws do not "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives" of the federal law, *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), I respectfully dissent.

Id. at 253.

The dissent further explained why Plaintiffs' claims would not frustrate any federal policy:

> The state statutory damages remedies for false and misleading advertisements would not frustrate the federal policy of protecting prescription drug consumers. The veracity of drug advertisements is essential to the protection of consumers. As stated in the legislative history to 21 U.S.C. § 352(n), "when a doctor is misled his patient's health is endangered." S. Rep. No. 87-1744 (1962), *reprinted in* 1962 U.S.C.C.A.N. 2884, 2904. Given that there are limitations to the FDA's oversight over prescription drug advertisements – both congressionally–imposed limitations, such as the lack of authority to require preapproval, 21 U.S.C. § 352(n), and practical limitations attendant to the sheer volume of drug advertisements

> in the media, *see* Donna U. Vogt, *CRS Report for Congress: Direct-to-Consumer Advertising of Prescription Drugs* 20 (Congressional Research Service, The Library of Congress 2005) (noting that in 2003 alone, the FDA received 38,000 advertisements from drug sponsors) – the supplementation of state-law remedies would seem to aid the FDCA's objectives and purposes, not frustrate them.

Id. at 258 (Cowen, J., dissenting).

Judge Cowen also exposed the flaw in the majority's conclusion that Congress intended to preempt all state law claims for deceptive marketing of prescription drugs:

> Congress's failure to provide a private remedy for persons injured by false and misleading advertisements further convinces me that the state law remedies are not preempted. As the Supreme Court stated in *Silk-wood* [v. *Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)], "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." 464 U.S. at 251; *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 450 (2005) ("[I]t seems unlikely that Congress considered a relatively obscure provision like § 136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability.").

> In addition, where the state law in question provides a long available form of compensation, it would be expected that Congress would express an intent to deprive injured parties of that compensation even more clearly. *See Bates*, 544 U.S. at 449. Here, the long history of state consumer protection statutes in this country (which, incidentally, were modeled after and coexisted with the FTCA, the FDCA's predecessor insofar as prescription drug advertising is concerned) adds force to the basic presumption against preemption. *See id.* at 449-50. That presumption has not been rebutted in this case.

Id. at 258-59.

REASONS FOR GRANTING THE PETITION

I. THIS CASE PRESENTS THE IMPORTANT QUESTION OF WHETHER CONGRESS INTENDED 21 U.S.C. § 352(n) TO PREEMPT ALL STATE-LAW CLAIMS FOR UNFAIR AND DECEPTIVE MARKETING OF PRESCRIPTION DRUGS

A. The Majority's Decision that Congress Intended 21 U.S.C. § 352(n) to Preempt All Claims Under State Law for Deceptive Marketing of Prescription Drugs is Directly At Odds With Congress's Explicit Statement that § 352(n) Preempts Only State Laws that are in "Direct and Positive Conflict" with § 352(n)

This petition involves the critically important issue of whether Congress has clearly and manifestly stripped states of their historical power to protect their citizens from unfair and deceptive marketing of prescription drugs. The majority in this case held that by enacting 21 U.S.C. § 352(n), Congress intended to preempt ***all*** state-law claims for false advertising of prescription drugs, even if those claims do not conflict with any regulation of or finding by the FDA. Specifically, the majority held that by "excluding advertisements covered by 21 U.S.C. § 352(n) and the regulations promulgated thereunder from the scope of 15 U.S.C. § 52, Congress signaled its intent to give the FDA exclusive authority to regulate prescription drug advertising." 499 F.3d at 253.

The majority's holding overlooks a clear statement of congressional intent to ***preserve*** state regulation of drug advertising. In 1962, Congress enacted the "Drug Amendments of 1962." P.L. 87-781 § 131, 76 Stat. 780 *et seq.* (Oct. 10, 1962). Section 131 of Public Law 87-781 amended § 502 of the FDCA by adding subsection (n), which was codified as 21 U.S.C. § 352(n). *Id.*, 76 Stat. 791-92. Subsection (n) states, in pertinent part, that:

> [N]o advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. §§ 52-57).[4]

The majority relied on this provision in holding that Congress intended to strip states of their historical authority to regulate prescription drug advertising. *See* 499 F.3d at 253.

The majority's ruling should be reviewed because it directly conflicts with Congress's clear statement to the contrary. Section 202 of the Drug Amendments of 1962, 76 Stat. 793, states:

> Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic

4. The FDA regulations for prescription drug advertising are set forth in 21 C.F.R. § 202.1.

> Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.

Despite § 202 of the Drug Amendments of 1962, the majority held that 21 U.S.C. § 352(n) preempts Plaintiffs' claims even though Plaintiffs' claims are not in direct and positive conflict with any FDA regulation or any FDA finding. The majority held that § 352(n) preempts Plaintiffs' claim even though the Court also stated: "To the extent that the complaint alleges that Zeneca marketed Nexium as superior to Prilosec, those claims of superiority might be actionable inasmuch as such comparisons are not supported by the labeling and therefore might be false or misleading." 499 F.3d at 246.

Given the clear statement of Congress that state law claims are preempted only if they are in "direct and positive conflict" with § 352(n), there is no need to consult the legislative history for the Drug Amendments Act of 1962. Nonetheless, the legislative history of P.L. 87-781 shows that the majority's holding that Congress intended § 352(n) to preempt all state-law claims for false advertising of prescription drugs is misguided. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 452 n.26 (2005) ("the lengthy legislative history is barren of any indication that Congress meant to abrogate most of the common-law duties long owed by pesticide manufacturers"). For example, the Senate Report focused on widespread deceptive marketing of prescription drugs and does not suggest that all state-law claims for false advertising are preempted.

See S. Rep. No. 87-1744 (1962), *reprinted in* 1962 U.S.C.C.A.N. 2884, 2904 ("Eminent medical authorities testified that much of the drug advertising is misleading and some is false. They further emphasized that when a doctor is misled his patient's health is endangered.").

In addition, the floor debate in the House supports the conclusion that Congress did not intend to preempt all state-law claims for false advertising. Congressman Smith of California stated that "if we are going to pass this law, someone ought to offer an amendment to make certain that the passage of this bill, which gives all of this power to the Department of Health, Education, and Welfare and the Food and Drug Administration, will not preempt any State laws." 108 Cong. Rec. 21046 (1962). Shortly thereafter, Congressman Harris of Arkansas, the primary House sponsor of the bill, stated that "there is nothing in this bill that in any way preempts the authority and prerogatives of the States." *Id.* at 21047. Congressman Schenck of Ohio agreed, stating that "[m]any very helpful State laws are in effect; many such laws in some instances are even stronger than Federal laws for the protection of human health in the public interest." *Id.* at 21056.

In light of the clear language of congressional intent ***not*** to strip states of their authority to protect their citizens from deceptive prescription drug advertising and the lack of any indication in the legislative history to the contrary, this Court should review the majority's erroneous interpretation of 21 U.S.C. § 352(n) in this case.

Finally, the majority's interpretation of § 352(n) should be reviewed for an additional reason. The majority held that § 352(n) preempts oral misrepresentations to doctors even though § 352(n) addresses only written matter. By its terms, § 352(n) applies only to "advertisements and ***other descriptive printed matter*** issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug. . . ." (Emphasis added.) Thus, § 352(n) cannot preempt state-law claims for oral misrepresentations to physicians, because it does not cover such claims.

B. The Majority's Holding that FDA Regulation of Prescription Drug Advertising Preempts All State Claims Conflicts With Decisions by this Court

The majority's conclusion that Plaintiffs' claims are preempted because of the nature of the regulations adopted by the FDA, 499 F.3d at 251-52, conflicts with this Court's preemption decisions. For instance, in *Bates*, this Court held that the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.* (2000 ed. and Supp. II) did not preempt the plaintiffs' state-law claims for damages. This Court looked only to the language of 7 U.S.C.S. § 136v(b) to determine whether the plaintiffs' claims were preempted. This Court stated: "Even if Dow had offered us a plausible alternative reading of § 136v(b) – indeed, even if its alternative were just as plausible as our reading of that text – we would nevertheless have a duty to accept the reading that disfavors pre-emption." 544 U.S. at 449. This Court further explained that the "long history of tort litigation against manufacturers of poisonous

substances adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Id.*[5]

Under the analysis set out in *Bates*, preemption cannot be found in this case based solely on the extent of the FDA regulations, because Congress established that state laws must be in "direct and positive conflict" with § 352(n) in order to be preempted. Thus, the only pre-emption issue in this case is whether Plaintiffs' claims directly and positively conflict with § 352(n). Nonetheless, the Third Circuit held that Plaintiffs' claims were barred by the doctrine of implied conflict preemption as a result of the FDA regulations concerning prescription drug advertising. This Court should review that ruling.

The majority's holding that FDA regulation of prescription drug advertising preempts Plaintiffs' claims is at odds with other decisions by this Court. In *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707 (1985), this Court stated:

> To infer pre-emption whenever an agency deals with a problem comprehensively is

5. Moreover, this Court held in *Bates* that FIFRA does not preempt state-law claims for sales agents' oral misrepresentations. 544 U.S. at 445 n.17 ("Because FIFRA defines labeling as 'all labels and all other written, printed, or graphic matter' that accompany a pesticide, § 136(p)(2), any requirement that applied to a sales agent's oral representations would not be a requirement for 'labeling or packaging.'").

> virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence. *See Jones v. Rath Packing Co.*, 430 U.S., at 525. [¶] Moreover, because agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretive statements, and responses to comments, we can expect that they will make their intentions clear if they intend for their regulations to be exclusive.

Id. at 717-18. Here, the FDA has not taken the position that its regulations preempt all state-law claims for deceptive advertising of prescription drugs. *See In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M: 05-1699 CRB, 2006 U.S. Dist. LEXIS 95500, at *71 (N.D. Cal. Aug. 18, 2006) ("The FDA has been silent with respect to the preemption of lawsuits challenging false claims in prescription drug advertisements. This silence suggests that the FDA does not intend its review of promotional materials to preempt false advertising claims."). *See also Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 888 (8th Cir. 2005) ("In light of the dearth of evidence about the EPA's intent, we cannot conclude that it was the 'clear and manifest purpose of [the EPA]' to prohibit states from requiring that pesticides used exclusively on hopper box seeds be colored or discolored"); *Ford Motor Co. v. Ins. Comm'r of Penn.*, 874 F.2d 926, 939 (3d Cir. 1989) ("precisely

because the regulatory scheme at issue in these cases is so detailed, we interpret the absence of clear preemptive language as indicative that Congress did not intend to displace state law entirely.").

Further, the authority cited by the majority does not support its holding that the FDA regulation of prescription drug advertising preempts Plaintiffs' claims. The majority relies on *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 369 (1986), in which this Court stated that "a federal agency acting within the scope of its congressionally delegated authority may pre-empt state regulation. *Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141 (1982); *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691 (1984)." *See* 499 F.3d at 249. Neither *Louisiana* nor either of the two cases cited therein stands for the proposition that federal regulations preempt state-law claims that are consistent with the regulations. In *Louisiana*, this Court held that § 220 of the Communications Act of 1934 "does not operate to pre-empt state depreciation regulation for intrastate ratemaking purposes." 476 U.S. at 378 (footnote omitted). In *Fidelity*, this Court held that the Federal Home Loan Bank Board's "due-on-sale regulation was meant to pre-empt ***conflicting*** state limitations on the due-on-sale practices of federal savings and loans." 458 U.S. at 159 (emphasis added). Finally, in *Capital Cities*, this Court held that states could not prohibit cable operators from carrying alcoholic beverage commercials, because the FCC had taken the formal position that the "subject areas this agency has preempted include, of course, signal carriage, pay cable, leased channel regulations, technical standards, access, and several aspects of franchisee responsibility." 467 U.S.

at 703 n.8. In contrast, the FDA has not taken the position that its regulations of prescription drug advertising preempt all state-law claims for false advertising of such drugs.

The majority also relies on *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), but *Geier* undermines the majority's holding. In *Geier*, the plaintiffs sought to compel the defendants to install airbags, even though federal regulations permitted the defendants to install "other passive restraint systems, such as automatic belts or passive interiors." *Id.* at 881. This Court held that the plaintiffs' claim "would have presented an obstacle to the variety and mix of devices that the federal regulation sought." *Id.* In contrast to *Geier*, Plaintiffs do not claim that Zeneca should be required to take steps that would frustrate the FDCA's purposes. To the contrary, this case concerns Zeneca's deceptive touting of Nexium as superior to Prilosec – an assertion that the FDA found lacking in support. Thus, Plaintiffs' claims do not stand as an obstacle to the enforcement of FDA regulations.

Further, the majority's reliance on § 337 of the FDCA, 499 F.3d at 252, is contrary to *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), in which this Court held that fraud-on-the-FDA claims under state law are preempted. This Court explained that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), such as to warrant a presumption against finding federal preemption of a state-law cause of action." *Id.* at 347. This Court then held that "the plaintiffs' state-law fraud-on-

the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law." *Id.* at 348. As this Court explained, "were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case." *Id.* at 353.

Judge Cowen's dissent below explains why *Buckman* does not support the majority's opinion:

> Unlike the claims in *Buckman*, plaintiffs' claims here do not exist by virtue of a violation of FDCA disclosure requirements. The state consumer protection statutes at issue existed long before the federal enactments. Moreover, the majority does not identify any actual conflicts between the federal regime and the state statutes. There is, for example, no cited risk that the availability of state-law remedies would conflict with a particular federal objective or a careful balancing of interests that the federal government has achieved in policing prescription drug advertising.

499 F.3d at 257. As Judge Cowen recognized, Plaintiffs do not claim that Zeneca should take steps that would frustrate the FDCA's purposes or FDA regulation. To the contrary, this case concerns Zeneca's deceptive marketing of Nexium as superior to Prilosec. Plaintiffs' claims are fully consistent with the FDA's explicit findings that Zeneca's clinical studies do not support a claim that Nexium is superior to Prilosec. Thus,

Plaintiffs' claims do not stand as an obstacle to the FDA's enforcement of its regulations.

In short, this case presents the important question of whether the majority misapplied established preemption doctrine in holding that Congress intended to preempt all state regulation of prescription drug advertising.

II. THE MAJORITY'S HOLDING THAT 21 U.S.C. § 352(n) AND THE REGULATIONS PROMULGATED THEREUNDER PREEMPT ALL STATE-LAW CLAIMS FOR UNFAIR AND DECEPTIVE MARKETING OF PRESCRIPTION DRUGS IS IN CONFLICT WITH DECISIONS BY STATE COURTS OF LAST RESORT AND BY FEDERAL COURTS OF APPEALS

The majority's holding is in conflict with decisions by federal courts of appeals and state courts of last resort. First, the majority's construction of § 352(n) is at odds with that of two state courts of last resort. In *Levine v. Wyeth*, 2006 Vt. 107 (2006), the Vermont Supreme Court affirmed a judgment for the plaintiff, who was injured as a result of being injected with the prescription drug Phenergan.[6] The Court rejected the defendant's argument that the "claims conflict with defendant's obligations under federal law regulating

6. A petition for a writ of certiorari is pending in this Court in *Wyeth v. Levine*. *See* 127 S. Ct. 2451 (May 21, 2007) ("The Soli-citor General is invited to file a brief in this case expressing the views of the United States.").

prescription drug labels." *Id.* at ¶ 1. In particular, the Court stated:

> Congress has expressed its purposes clearly, not only in the general sense that the statute was intended to "protect the public, "but also more specifically, with respect to the FDCA's preemptive effect. In the 1962 amendments to the FDCA, Congress included a clause expressly limiting the preemptive effect of the statute: "Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law ... unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962 (Harris Kefauver Act), Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962).
>
> This amendment essentially removes from our consideration the question of whether common-law tort claims present an obstacle to the purposes and objectives of Congress. Congress intended that the FDCA would leave state law in place except where it created a "direct and positive conflict" between state and federal law. Drug Amendments § 202. This language "simply restates the principle that state law is superseded in cases of an actual conflict with federal law such that 'compliance with both federal and state regulations is a physical impossibility.'" *See S. Blasting Servs., Inc. v.*

> *Wilkes County*, 288 F.3d 584, 591 (4th Cir. 2002) (interpreting "direct and positive conflict" language in the preemption clause of a federal statute governing explosive materials to allow states to "impose more stringent requirements than those contained in the federal regulations") (quoting *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985)). In other words, under any circumstances where it is possible to comply with both state law and the FDCA, the state law in question is consistent with the purposes and objectives of Congress. Thus, our discussion above regarding defendant's impossibility argument, *supra* 21-23, provides a complete answer to the question of pre-emption.

Id. at ¶¶ 26-27 (footnote omitted).

The majority's interpretation of § 352(n) also is in conflict with the New Jersey Supreme Court's decision in *Perez v. Wyeth Labs. Inc.*, 161 N.J. 1, 734 A.2d 1245 (1999). In *Perez*, the Court held that the learned intermediary doctrine "does not confer on pharmaceutical manufacturers a license to mislead or deceive consumers when those manufacturers elect to exercise their right to advertise their product directly to such consumers." *Id.* at 32, 734 A.2d at 1264. The Court noted that the "FDA is authorized to regulate advertisements for prescription drugs pursuant to 21 U.S.C.A. Section 352(n) of the Food, Drug and Cosmetic Act." *Id.* at 22, 734 A.2d at 1258. The Court did not hold that § 352(n)

preempted the plaintiffs' state-law claims but rather explained that "FDA regulations are pertinent in determining the nature and extent of any duty of care that should be imposed on pharmaceutical manufacturers with respect to direct-to-consumer advertising." *Id.* at 24, 734 A.2d at 1259. The Court then held that a "rebuttable presumption [of legality] should apply when a manufacturer complies with FDA advertising, labeling and warning requirements." *Id.*

Thus, the holding by the New Jersey Supreme Court in *Perez* is in conflict with the holding by the majority in this case. Plaintiffs in this case allege that the FDA found that Zeneca's studies do not support the assertion that Nexium is superior to Prilosec. Nonetheless, Zeneca advertised and otherwise marketed Nexium as superior to Prilosec. Under *Perez*, the rebuttable presumption of lawful behavior would not apply, because Zeneca did not comply with FDA requirements. Indeed, the Third Circuit stated that "[t]o the extent that the complaint alleges that Zeneca marketed Nexium as superior to Prilosec, those claims of superiority might be actionable inasmuch as such comparisons are not supported by the labeling." 499 F.3d at 246. Nonetheless, the Third Circuit held that § 352(n) pre-empted Plaintiffs' claims. Thus, Plaintiffs' claims could be brought in New Jersey state court but not in the United States District Court for New Jersey.

Moreover, in the forty-five years since enactment of § 352(n), no court other than the majority in this case has held by enacting § 352(n), Congress intended to preempt all state-law claims for deceptive marketing of prescription drugs. Federal and state courts have long

permitted state-law claims for deceptive marketing of prescription drugs. *See, e.g., Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 350 (2d Cir. 2003) (reversing dismissal of action under state law for false advertising of prescription drug Rezulin, because "courts have long recognized the right of [plaintiffs] to recover from drug companies amounts that were overpaid due to illegal or deceptive marketing practices"). Thus, courts have routinely permitted claims under state law for false advertising of prescription drugs.[7]

---

7. *See In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 523 (3d Cir. 2004) (approving settlement of a case for violation of the Sherman Act and the Delaware Consumer Fraud Act, in which "DuPont allegedly issued a variety of false and misleading communications to convince health care professionals, government agencies, and the public that Coumadin was safer and more effective than Barr's generic warfarin sodium product"); *Hill v. Searles Labs.*, 884 F.2d 1064, 1070 (8th Cir. 1989) (reversing summary judgment for pharmaceutical company in product liability case, in part because "IUD manufacturers, through mass advertising and merchandising practices, generated a general sense of product quality, making it difficult for con-sumers to fully understand the risks involved with the use of an IUD"); *Mirkin v. Wasserman*, 5 Cal. 4th 1082, 1112-13 (1993) ("Courts in California and other states have applied the principle of indirect reliance to the situation in which a manufacturer of a prescription drug or medical device has misrepresented its product's safety and effectiveness to the medical profession."). *Cf. Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 939 (8th Cir. 2005) (rejecting defendant's argument that "plaintiffs may not bring Lanham Act false advertising claims involving FDCA or FDA regulations because there is no private right of action to enforce these provisions, Congress did not intend for the Lanham Act to be a vehicle for enforcing the provisions indirectly, and the area is within the expertise of the FDA").

The majority's decision in this case is also at odds with numerous decisions in which courts have held that the phrase "direct and positive conflict" demonstrates that Congress intended ***not*** to preempt state-law claims. For example, the "Firearms" chapter of the criminal code contains 18 U.S.C. § 927, which states:

> No provision of this chapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which such provision operates to the exclusion of the law of any State on the same subject matter, unless there is a direct and positive conflict between such provision and the law of the State so that the two cannot be reconciled or consistently stand together.

In *Thrall v. Wolfe*, 503 F.2d 313, 317 (7th Cir. 1974), the Seventh Circuit explained that § 927 "was doubtless inserted for the purpose of avoiding a claim of preemption." The highest courts of three states agree. *See City of Gary v. Smith & Wesson Corp.*, 801 N.E.2d 1222, 1237 (Ind. 2003) ("But federal legislation has expressly denied any intent to preempt state laws regulating guns. 18 U.S.C. 927 (2000)."); *State v. Hernandez-Mercado*, 124 Wn.2d 368, 879 P.2d 283 (1994) (citing 18 U.S.C. § 927 in holding that "RCW 9.41.170 does not directly conflict with, nor is it inconsistent with, the federal provision prohibiting possession of a firearm by non-citizens (aliens) who are 'illegally or unlawfully in the United States'. RCW 9.41.170 is thus not preempted by federal firearms laws."); *Carfield v. State*, 649 P.2d 865, 873 (Wyo. 1982) (quoting 18 U.S.C. § 927 in rejecting argument that federal law preempted state law

banning certain felons from possessing a firearm and explaining that "comparison of the Wyoming statute with the federal laws demonstrates no conflict. Indeed the statutes are complementary in their application and can be easily reconciled. Since the clear intention of Congress was not to preempt this field, but rather to supplement existing state law in the area, and because of the difference in the statutory elements, we find no merit in this contention of the appellant.").

A similar preemption provision is contained in the federal law governing explosive materials, which is codified at 18 U.S.C. §§ 841-848 (2000). Section 848, entitled "Effect on State law," provides:

> No provision of this chapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which such provision operates to the exclusion of the law of any State on the same subject matter, unless there is a direct and positive conflict between such provision and the law of the State so that the two cannot be reconciled or consistently stand together.

In *S. Blasting Servs., Inc. v. Wilkes County*, 288 F.3d 584 (4th Cir. 2002), the Fourth Circuit rejected the plaintiffs' argument that federal law preempts ordinances regulating the use of explosives. After quoting § 848, the court stated:

> This statutory language makes clear that Congress did not intend to occupy the field of licensing and regulating explosives operations.

> In preemption analysis, "the purpose of Congress is the ultimate touchstone." *Retail Clerks Int'l Ass'n, Local 1625 v. Schermerhorn*, 375 U.S. 96, 103, 11 L. Ed. 2d 179, 84 S. Ct. 219 (1963). Here Congress has stated in the clearest of terms that it was not preempting local efforts to regulate the explosives industry, absent a direct and positive conflict with the federal standards. In fact, as the district court recognized, "§ 848 is designed to limit the preemptive scope" of the federal law and expressly "disclaims any intent to occupy the field." *S. Blasting*, 162 F. Supp. 2d at 462.

Id. at 590. Thus, the majority decision in this case is at odds with the holdings of numerous other courts.

CONCLUSION

Petitioners' petition for a writ of certiorari should be granted.

Respectfully submitted,

STEVE W. BERMAN
Counsel of Record
CRAIG R. SPIEGEL
HAGENS BERMAN SOBOL SHAPIRO LLP
1301 Fifth Ave., Suite 2900
Seattle, Washington 98101
(206) 623-7292

Attorneys for Petitioners

(Additional Counsel listed on inside cover)

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT FILED AUGUST 17, 2007

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Case No: 05-5340

PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND on behalf of itself and all others similarly situated; JOSEPH MACKEN; COMMISSIONER LINDA A. WATTERS,

Appellants

v.

ZENECA INC; ASTRAZENECA PHARMACEUTICALS LP

June 5, 2007, Argued
August 17, 2007, Filed

Before: SMITH, COWEN, and SILER, Circuit Judges.*

OPINION OF THE COURT

SMITH, *Circuit Judge.*

The Pennsylvania Employees Benefit Trust Fund, Joseph Macken, and Linda Watters ("plaintiffs") sued Zeneca, Inc. and AstraZeneca Pharmaceuticals, L.P.

* The Honorable Eugene E. Siler, Senior Circuit Judge for the United States Court of Appeals for the Sixth Circuit, sitting by designation.

(collectively referred to as "Zeneca") in the United States District Court for the District of Delaware, asserting that Zeneca engaged in deceptive conduct in the advertising of its new drug Nexium. Claim One alleged unlawful advertising under the Delaware Consumer Fraud Act ("DCFA"). The second claim alleged violations of the consumer protection statutes of the 50 states for false, misleading, and deceptive advertising. Claim Three alleged unjust enrichment, and stated claims under Delaware common law for restitution, disgorgement, and constructive trust. The fourth claim was for negligent misrepresentation, and it alleged that the company released misleading advertisements for the prescription drug Nexium. The District Court dismissed the complaint with prejudice.

This appeal presents two principal questions: (1) whether the DCFA exemption for advertising regulated by the Federal Trade Commission applies to the facts of this case; and (2) whether federal law preempts the plaintiffs' state consumer protection claims. The plaintiffs also assert that primary jurisdiction was an improper basis for dismissal, that their unjust enrichment claim was improperly dismissed on the ground that they had not pled individual reliance, and that they should have been allowed to amend their complaint. We will affirm the judgment of the District Court.[1]

---

1. The District Court had diversity jurisdiction under 28 U.S.C. § 1332(d)(2) and (6), which confers federal jurisdiction over class actions where "any member of a class of plaintiffs is a citizen of a State different from any defendant" and the amount in controversy exceeds $5,000,000. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1291 and 1294.

Appendix A

I.

On February 11, 2005, the plaintiffs[2] filed a putative class action against Zeneca, alleging that Zeneca's marketing campaign for Nexium[3] was deceptive because it misleadingly advertised Nexium as an improvement on Prilosec. Nexium and Prilosec are both proton-pump inhibitors, drugs that treat gastroesophageal reflux disease ("GERD") and erosive esophagitis, conditions that are commonly known as acid reflux disease and frequent heartburn. Prilosec was a profitable drug for Zeneca, and had sales of $6 billion in 2000. The patent for Prilosec was due to expire in 2001, at which point it would be available for sale as the generic drug omeprazole. On February 14, 2001, Zeneca obtained approval from the Food and Drug Administration ("FDA") for final labeling on Nexium for healing of erosive esophagitis, maintenance of healing of erosive esophagitis, and treatment of symptomatic GERD (i.e., heartburn).

---

2. On April 13, 2006, Zeneca filed a motion to dismiss the appeal as to seven of the original ten plaintiffs on the ground that the notice of appeal included only the Pennsylvania Employees Benefit Trust Fund, Joseph Macken, and Linda Watters. The three named plaintiffs contested the motion to dismiss, which is now before us. Because of our disposition of this case, we need not reach this issue. We will deny the motion to dismiss as moot.

3. Nexium is the proprietary name for esomeprazole magnesium.

Appendix A

One published clinical study of Nexium compared both 20 mg and 40 mg doses of Nexium to the approved 20 mg dose of Prilosec. The data from this study showed that 40 mg of Nexium had a statistically significant healing rate over 20 mg of omeprazole. This study was among those used to obtain FDA approval of Zeneca's new drug application for Nexium. The FDA later determined that Nexium should be approved at recommended dosages of 20 mg or 40 mg once daily, for four to eight weeks, for the healing of erosive esophagitis, and at 20 mg for both maintenance of healing of erosive esophagitis and symptomatic GERD.

In their complaint, plaintiffs alleged that the large-scale promotional campaign for Nexium, which included both physician-directed marketing and direct-to-consumer advertising, was misleading because it incorrectly represented that Nexium was superior to Prilosec. The plaintiffs asserted that a dose of 40 mg is not needed in most patients and a fair comparison of 20 mg of Nexium to 20 mg of Prilosec would not have proven Nexium to be superior. The plaintiffs also contended that Zeneca initially sold Nexium at a price below Prilosec in order to establish brand loyalty, but "then raised the price of Nexium while the price of Prilosec dropped. [Nexium] now sells for $4.09 per pill versus $0.67 per pill or less for Prilosec." On November 8, 2005, the District Court granted Zeneca's motion to dismiss for failure to state a claim.

We review the grant of a motion to dismiss de novo, accepting all well-pleaded allegations as true and

drawing all reasonable inferences in favor of the plaintiffs. *In re Adams Golf, Inc. Sec. Litig.*, 381 F.3d 267, 273 (3d Cir.2004); *In re Alpharma Sec. Litig.*, 372 F.3d 137, 146 (3d Cir.2004). Review of the denial of leave to amend is for abuse of discretion. *Hill v. City of Scranton*, 411 F.3d 118, 134 (3d Cir.2005).

II.

The Application of the DCFA Exemption

The first issue raised on appeal is whether FDA approval of prescription drug labeling and regulation of advertising brings the plaintiffs' claims within the DCFA exemption of "any advertising or merchandising practice" that is compliant with Federal Trade Commission regulations. The purpose of the DCFA is "to protect consumers and legitimate business enterprises from unfair or deceptive merchandising practices in the conduct of any trade or commerce in part or wholly within this State." 6 Del. Code Ann. § 2512. The DCFA proscribes

> The act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether

> or not any person has in fact been misled, deceived or damaged thereby. . . .

6 Del. Code Ann. § 2513(a). The exemption language in the DCFA at issue states that "[t]his section shall not apply . . . [t]o any advertisement or merchandising practice which is subject to and complies with the rules and regulations, of and the statutes administered by, the Federal Trade Commission. . . ." 6 Del. Code Ann. § 2513(b)(2). The District Court concluded that all of the advertising materials cited by the plaintiffs in their complaint "are related to the safety and efficacy of Nexium, are consistent with the FDA-approved labeling and, therefore, are not actionable under the DCFA pursuant to 6 Del. C. § 2513(b)(2)."

Plaintiffs argue that the exemption should be read more narrowly than the District Court read it, and that, properly construed, the exemption did not protect Zeneca's conduct. In particular, plaintiffs assert that (1) the exemption is limited to conduct expressly approved by the FTC; (2) the FDA did not explicitly approve Zeneca's marketing campaign; and (3) Zeneca's marketing deviated from statements approved by the FDA for Nexium's label. Zeneca points to the broad prohibitions in 15 U.S.C. §§ 45 and 52, which declare unlawful unfair methods of competition and the dissemination of false advertisements, as proof that prescription drug advertising is subject to the statutes administered by the FTC.

As a preliminary matter, we decline to read the DCFA exemption to require that an advertisement or merchandising practice must be expressly approved by the FTC in order to qualify for the exclusion. The plain language of § 2513(b)(2) requires only that the conduct be subject to and compliant with rules and regulations created by the FTC and the statutes administered by that agency. Accordingly, the lack of express FTC approval of the Nexium marketing campaign is not a basis for declaring the statutory exemption inapplicable.

We are left, then, with the thornier question presented by plaintiffs' assertion that the exemption's reach does not extend to matters subject to FDA oversight. By congressional decree, the FTC and the FDA originally shared jurisdiction over prescription drug advertising. *See* Pub. L. No. 87-781, 76 Stat. 791-92 (1962) (codified as amended at 21 U.S.C. § 352(n)); *see also* 15 U.S.C. §§ 45 and 52; 21 U.S.C. § 352(n) (removing any "advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs," from the purview of the provisions of 15 U.S.C. §§ 52-57); 21 U.S.C. § 393(b)(1) ("The [FDA] shall ... promote the public health by ... taking appropriate action on the marketing of regulated products in a timely manner"). Because Congress gave the agencies concurrent jurisdiction with respect to regulating prescription drug advertising until the FDA promulgated regulations, the FDA and FTC established

their own interim division of responsibilities.[4] In the Working Agreement Between FTC and Food and Drug Administration, 36 Fed.Reg. 18,539 (Sept. 16, 1971), the two agencies agreed that "[t]he Food and Drug Administration has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising." This statement does not preclude FTC regulation of prescription drug advertising, but rather notes the agencies' mutual understanding that the FDA will take the lead in regulating such activities, subject to the concurrent jurisdiction of both agencies. The statement explicitly limits the FDA's primary responsibility to determining the veracity of the advertising claims; it does not suggest that regulating technically true, but potentially misleading, advertisements is the exclusive domain of the FDA. Accordingly, this arrangement alone does not remove the claims regarding Nexium advertising from the purview of regulations and statutes administered by the FTC. However, the FDA's subsequent promulgation of regulations for prescription drug advertising effectively eliminated the FTC's authority in this area.

Even if Zeneca can show that the marketing was almost identical to the specifically authorized labeling, the FDA is not merely acting as the FTC's proxy in regulating prescription drug advertising. The FDA has responsibility for regulating the advertising of

---

4. The FDA promulgated preliminary regulations on prescription drug advertising in 1975. 40 Fed.Reg. 14106 (Mar. 27, 1975).

prescription drugs that is independent of any delegation from the FTC.[5]

Although there is an affinity between FTC and FDA guidance[6] and the scope of the Federal Trade

5. In *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir.1990), we summarized the division of regulatory authority in this manner: "the FDA regulates the labeling of OTC drugs while the FTC monitors the advertising for these drugs." *Id.* at 227. The facts and law at issue in *Sandoz* are distinguishable and we need not follow its dicta in this case. In *Sandoz*, the Court was concerned with the question of whether a Lanham Act plaintiff needs to show only that the defendant's advertising claims of its own drug's effectiveness are inadequately substantiated under FDA guidelines, or whether the plaintiff must also show that the claims are literally false or are misleading to the public. *Id.* at 224, 229. The dispute in Sandoz was also over the marketing of an over-the-counter drug. OTC drugs and prescription drugs are subject to different rules and regulations. *Compare id.* at 227 ("The FTC has the authority under Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 & 52, to find that an inadequately substantiated advertising claim regarding a non-prescription drug is deceptive or misleading, and thus illegal."), *with* 21 C.F.R. § 202.1. Thus, our opinion in *Sandoz* has little applicability to this case.

6. For example, Zeneca points to FDA guidance that expressly permits drug manufacturers to describe newly approved drugs as "new" for six months after their launch, see http:// www. fda. gov/ cder/ ddmac/ FAQS. HTM (explaining that "DDMAC [the Division of Drug Marketing, Advertising and Communications] generally considers that 'New' is an accurate description of the marketing phase for six months from the time a product is initially marketed"), and the FTC's similar opinion that there is a "tentative outer limit for use of the claim [that a product is 'new'] . . . [of] a period of time

(Cont'd)

Commission Act ("FTCA") is broad, the reasoning of the District Court rests on the premise that advertising that is based upon labeling approved by the FDA falls within the DCFA exemption. This is an unsupportable extension of the language of § 2513(b)(3).

The distinction between labeling and marketing is significant for regulatory purposes. Although there is often a strong correlation between a drug's labeling and marketing[7], federal approval of labeling does not

---

(Cont'd)

no longer than 6 months." Permissible Period of Time During Which New Product May Be Described as "New," 32 Fed.Reg. 6023, 6023 (Apr. 14, 1967). The mere fact that the agencies have similar interpretations only shows inter-agency consistency; it does not show that the FTC was the regulating entity.

7. 21 C.F.R. § 202.1(e)(4)(i)(a) ("The advertisement shall present information from labeling required, approved, or permitted in a new-drug application relating to each specific side effect and contraindication in such labeling that relates to the uses of the advertised drug dosage form(s). . . ."); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed.Reg. 3922, 3960 (Jan. 24, 2006) ("[S]tatements made in promotional labeling and advertisements must be consistent with all information included in labeling under proposed § 201.57(c) to comply with current §§ 201.100(d)(1) and 202.1(e)."); Professional Product Labeling; Public Meeting, 60 Fed.Reg. 52196, 52196 (Oct. 5, 1995) ("The approved labeling serves as the basis for fulfilling the requirement of the Federal Food, Drug, and Cosmetic Act ... that prescription drug advertising include 'information in brief summary relating to side effects, contraindications, and effectiveness.' (section 502(n) of the Act (21 U.S.C. § 352(n))).").

necessarily authorize marketing practices. Labeling is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). It functions as "the primary mechanism through which FDA and drug manufacturers communicate essential, science-based prescribing information to health care professionals." Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed.Reg. 81082, 81082 (Dec. 22, 2000); *see also* 21 C.F.R. § 202.1(*l*)(2) (stating that material such as "[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, [etc.] . . . descriptive of a drug and references published (for example, the 'Physicians Desk Reference') *for use by medical practitioners, pharmacists, or nurses*, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling" (emphasis added)).

In contrast, advertisements are published in journals, magazines, and newspapers, and are broadcast through media such as television and radio. Advertisements also come in the form of physician-directed pitches by sales representatives, computer programs, and electronic media. *See* 21 C.F.R. § 202.1(*l*)(1). Although advertising may also serve as a mechanism to distribute safety information about a drug,

its primary purpose—unlike labeling—is not to promote safety but rather to promote market expansion. *See,e.g.*, Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Evaluation of Variations in Content and Format of the Brief Summary in Direct-to-Consumer Print Advertisements for Prescription Drugs, 72 Fed.Reg. 11889, 11889 (March 14, 2007) ("Although advertising of prescription drugs was once primarily addressed to health professionals, increasingly consumers have become a target audience, as DTC advertising has dramatically increased in the past few years.... Frequently, sponsors print in small type, verbatim, the risk-related sections of the approved product labeling (also called the package insert, professional labeling, or prescribing information). This labeling is written for health professionals, using medical terminology."). Zeneca has shown, through documentary evidence, that the FDA approved its labeling. However, the plaintiffs contend that the advertising differed sufficiently from the labeling such that it cannot also be considered to have been approved by the FDA.

Approval of a new drug application occurs "after [the FDA] determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, *and labeling*...." 21 C.F.R. § 314.105(c) (emphasis added). The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, requires that applicants for new drug applications submit "[c]opies of the label and all labeling for the drug product," 21 C.F.R. § 314.50(e)(2)(ii), and it specifically prohibits

misbranding of drugs. "A drug or device shall be deemed to be misbranded . . . if its labeling is false or misleading in any particular." 21 U.S.C. § 352(a); 21 C.F.R. § 1.21(a)(i)-(ii) ("Labeling of a ... drug ... shall be deemed to be misleading if it fails to reveal facts that are: (1) Material in light of other representations made or suggested by statement, word, design, device or any combination thereof; or (2) Material with respect to consequences which may result from use of the article under: (i) The conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual."). The FDA may refuse to approve an application on the grounds that "[t]he proposed labeling is false or misleading in any particular." 21 C.F.R. § 314.125(b)(6). Thus, to the extent that the advertising statements regarding Nexium were consistent with statements used in the labeling approved by the FDA, the FDA has determined that they are not false or misleading.[8]

---

8. The FDA's determination that a statement is not false or misleading is, of course, distinct from a determination that the presentation of that statement is not misleading. The regulations provide that

> An advertisement may be false, lacking in fair balance, or otherwise misleading ... if it ... [f]ails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

(Cont'd)

Appendix A

The FDA's Division of Drug Marketing, Advertising and Communications advises drug makers on proposed advertising and promotional labeling, in accordance with 21 C.F.R. § 202.1(j)(4). However, this review process is largely voluntary. *Id.* ("Any advertisement may be submitted to the Food and Drug Administration prior to publication for comment."); *but see* 21 C.F.R. § 314.81(b)(3) ("The applicant shall submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product."). Section 352(n) of the FDCA exempts the content of any advertisement from pre-release Secretarial scrutiny, except in "extraordinary circumstances." 21 U.S.C. § 352(n)(3)(A).

Whether Zeneca is correct in its assertion that the complaint is fundamentally "based on" the labeling is a legal question. The complaint attacks both the actual marketing tactics used by Zeneca, as well as the studies upon which FDA approval was based. To the extent that the complaint alleges that Zeneca marketed Nexium as superior to Prilosec, those claims of superiority might be actionable inasmuch as such comparisons are not supported by the labeling and therefore might be false or misleading. Although we need not decide this question now, we note that the FDA's regulations require

---

(Cont'd)

21 C.F.R. § 202.1(e)(7)(viii). Through these regulations, the FDA has gone beyond the mere supervision of veracity in advertising statements to examine how the information is presented.

prescription drug advertisements to comport with approved labeling. *See, e.g.*, 21 C.F.R. § 202.1(e)(3)(iii) ("The information relating to side effects and contraindications shall disclose each specific side effect and contraindication . . . contained in required, approved, or permitted labeling for the advertised drug. . . ."); Thomas A. Hayes, *Drug Labeling and Promotion: Evolution and Application of Regulatory Policy*, 51 Food & Drug L.J. 57, 62 (1996) (explaining that, under the regulations, "advertising claims may be based either on substantial evidence or on substantial clinical experience," but the standard for labeling is substantial evidence); *see* 21 C.F.R. § 201.56(a)(3) (disallowing claims or suggestions of drug use on labeling if there is a lack of substantial evidence).

Congress expressly gave the FDA authority over prescription drug advertising in the FDCA. The FDCA lists a number of required elements of prescription drug advertising and states that "no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 52 to 57 of Title 15." 21 U.S.C. § 352(n). Section 52 of Title 15 declares unlawful the dissemination of false advertisements. Subsection 352(n) of the FDCA was added in 1962. Pub. L. 87-781, § 131(a).

The DCFA became law in 1965. *See Brandywine Volkswagen, Ltd. v. State Dept. of Community Affairs*

and Econ. Dev., Div. of Consumer Affairs, 312 A.2d 632, 633 (Del.1973) (citing 55 Del.L., Ch. 46.). In enacting this statute, the Delaware General Assembly expressed its intent "to protect consumers and legitimate business enterprises from unfair or deceptive merchandising practices." 6 Del. Code Ann. § 2512. The legislature also explicitly declared its "intent . . . that such practices be swiftly stopped and that this subchapter shall be liberally construed and applied to promote its underlying purposes and policies." *Id.* Reading the exemption in § 2513(b)(2) to exclude from the scope of the DCFA marketing practices that are subject to the rules and regulations of the FDA, and which are required to be based on labeling that is expressly approved and required by the FDA, improperly broadens the reach of the exemption beyond its explicit limitation to practices that are compliant with FTC rules and regulations. We will not rewrite the text of the exemption to include regulation of activities that are not within the FTC's authority. Accordingly, we hold that the District Court erred in ruling that the plaintiffs' claims were not actionable under the DCFA.

III.

Preemption

The District Court further concluded that the Nexium advertisements that complied with the FDA-approved labeling were not actionable under the state consumer protection laws because those laws were preempted by federal law. The District Court correctly

analyzed this issue under the rubric of implied conflict preemption. Plaintiffs assert that the District Court's application of federal preemption is incorrect because there is not an irreconcilable conflict between the state consumer fraud laws and the FDCA. In particular, the plaintiffs argue that the approval of Nexium's labeling did not extend to an assertion of Nexium's superiority over Prilosec.

Implied conflict preemption renders state law "without effect" when, without "express congressional command," state law conflicts with federal law. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). As the Supreme Court has explained, "[t]his question is basically one of congressional intent. Did Congress, in enacting the Federal Statute, intend to exercise its constitutionally delegated authority to set aside the laws of a State? If so, the Supremacy Clause requires courts to follow federal, not state, law." *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 30, 116 S.Ct. 1103, 134 L.Ed.2d 237 (1996). The Court has "found implied conflict pre-emption ... where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " *Sprietsma v. Mercury Marine, a Div. of Brunswick Corp.*, 537 U.S. 51, 64-65, 123 S.Ct. 518, 154 L.Ed.2d 466 (2002) (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287, 115 S.Ct. 1483, 131 L.Ed.2d 385 (1995) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S.Ct. 399, 85 L.Ed. 581 (1941))). Thus, the question presented here is whether state consumer fraud laws pose an obstacle to the FDA's

congressionally-mandated regulation of prescription drug advertising.

For purposes of this case, the critical characteristic of the FDCA is that it regulates the safety of drugs. The FDCA states that the mission of the FDA is to "(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner; (2) with respect to such products, protect the public health by ensuring that . . . (B) human . . . drugs are safe and effective." 21 U.S.C. § 393(b). Prior to the introduction of a new drug, the FDA must find that the "drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d) (explaining in detail the seven-part test that the FDA uses in determining whether to approve a drug); *see also Grinspoon v. DEA*, 828 F.2d 881, 887 (1st Cir.1987). As part of this process, the FDA must find that there is "substantial evidence that the drug will have the effect it purports or is represented to have. . . ." *Id.* During the approval process, the Secretary may determine, "based on relevant science, that data from *one* adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness. . . ." *Id.* (emphasis added). Such data and evidence constitute "substantial evidence" under 21 U.S.C. § 355.

Appendix A

Section 352(n) lists three items that prescription drug advertising must include: (1) the actual name of the drug, if a trade or brand name is used; (2) the ingredient list and quantitative formula for each ingredient; and (3) a brief summary of side effects, contraindications, and effectiveness. The subsection is called the "brief summary" provision. It requires a true statement of these three items in the brief summary included in advertisements. The statute explains that, to the extent that an advertisement complies with subsection (n) in listing the three items, it is not subject to the false advertising provisions of the FTCA. However, as noted above, § 352(n) requires only pre-release approval of advertisements in "extraordinary circumstances."

Pursuant to its regulatory authority over prescription drug advertising, the FDA promulgated regulations that lay out the specific requirements for advertising prescription drugs. *See* 21 C.F.R. § 202.1. In particular, the regulations stipulate that an advertisement does not include a "true statement" if it is

> [F]alse or misleading with respect to side effects, contraindications, or effectiveness; or [i]t fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug in that the information relating to effectiveness . . . is not fairly balanced by a presentation of a summary

> of true information relating to side effects and contraindications of the drug . . . ; [or] [i]t fails to reveal facts material in the light of its representations or material with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement.

21 C.F.R. § 202.1(e)(5). The regulation includes an extensive, but non-exhaustive, 20-factor list of reasons why "[a]n advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading. . . ." 21 C.F.R. § 202.1(e)(6)(i)-(xx).[9] The subsequent subsection explains the circumstances under which "[a]n advertisement *may* be false, lacking in fair balance, or otherwise misleading. . . ." 21 C.F.R. § 202.1(e)(7) (emphasis added). The regulations further state that

---

9. Subsection (e)(6)(ii) deems an advertisement misleading if it "[c]ontains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience." 21 C.F.R. § 202.1(e)(6)(ii). Although the FDA did not explicitly approve Zeneca's advertising, the FDA did approve Nexium's labeling, which included clinical studies that showed statistically significant healing rates for 40 mg of Nexium as compared to 20 mg of omeprazole. The regulations explain that the clinical studies section "must discuss those clinical studies that facilitate an understanding of how to use the drug safely and effectively. Ordinarily, this section will describe the studies that support effectiveness for the labeled indication(s). . . ." 21 C.F.R. § 201.57(c)(15).

"[d]issemination of an advertisement not in compliance with this paragraph shall be deemed to be an act that causes the drug to be misbranded. . . ." 21 C.F.R. § 202.1(j)(3). The FDA explains that "[a]ny advertisement may be submitted to the Food and Drug Administration prior to publication for comment," but does not require that manufacturers submit their ads for preapproval. 21 C.F.R. § 202.1(j)(4). However, the FDA does require manufacturers to submit advertising specimens "at the time of initial publication of the advertisement for a prescription drug product." 21 C.F.R. § 314.81(b)(3)(i) (requiring transmittal of the advertisement with Form FDA-2253).

The degree of discretion inherent in the regulations demonstrates that the FDA envisioned itself occupying an ongoing and extensive role in the supervision of prescription drug advertising. *See, e.g.*, 60 Fed.Reg. at 44210 ("In order to carry out the public health protection purposes of the act, FDA: . . . (3) monitors drug labeling and prescription drug advertising to help ensure that they provide accurate information about drug products."); Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed.Reg. 36,677, 36,677 (Sept. 9, 1985) ("FDA will continue to regulate prescription drug advertising, regardless of its intended audience, in accordance with section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) and the implementing regulations (21 CFR Part 202)."). Furthermore, Congress shared

that vision. *See* 21 U.S.C. § 352(n); 21 U.S.C. § 393(b)(1).[10] However, neither the language of the FDCA nor the regulations explicitly preempt state consumer fraud law.

The central tenet of preemption analysis is that "'[t]he purpose of Congress is the ultimate touchstone'" in determining whether state law is preempted. *Cipollone*, 505 U.S. at 516, 112 S.Ct. 2608 (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103, 84 S.Ct. 219, 11 L.Ed.2d 179 (1963)).[11] However, the Supreme Court

---

10. Congress did not always concede jurisdiction over prescription drug advertising to the FDA. When the FDCA was passed in 1938, Congress left the authority to police "unfair or deceptive acts or practices in or affecting commerce" with the FTC. Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. § 301 *et seq.*; Wheeler-Lea Act, 52 Stat. 111, ch. 49 (1938) (amending section 5 of the FTCA, Pub. L. No. 63-203, 38 Stat. 717, 719 (1914) (prohibiting "unfair methods of competition in commerce")). It was not until the 1962 Kefauver-Harris Drug Amendments, which enacted section 502(n) of the FDCA, that regulatory authority over prescription drug advertising was transferred to the FDA. Pub. L. No. 87-781, § 131(a), 76 Stat. 791-92 (1962). For a more complete recitation of the history of direct-to-consumer advertising, see Francis B. Palumbo and C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 Food & Drug L.J. 423, 424-31 (2002).

11. The dissent correctly notes that "we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947). The prevention of consumer fraud has traditionally been within the purview of the

(Cont'd)

has long indicated that agency regulations are also a source of preemptive law. *See, e.g., Louisiana Public Serv. Comm'n v. FCC*, 476 U.S. 355, 369, 106 S.Ct. 1890, 90 L.Ed.2d 369 (1986) ("Pre-emption may result not only from action taken by Congress itself; a federal agency acting within the scope of its congressionally delegated authority may pre-empt state regulation."). In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996), the Court considered FDA regulations in the course of its preemption analysis and noted that, under the regulations, "state requirements are pre-empted 'only' when the FDA has established 'specific counterpart regulations or ... other specific requirements applicable to a particular device.' " *Id.* at 498, 116 S.Ct. 2240 (quoting 21 C.F.R. § 808.1(d)). While the Court emphasized congressional intent in determining whether preemption was appropriate, *id.* at 485-86, 116 S.Ct. 2240, the Court also looked to the "statutory and regulatory language" in evaluating "the allegedly preempting federal requirement and the allegedly pre-empted state requirement. . . ." *Id.* at 500, 116 S.Ct. 2240.

(Cont'd)

states. This historical preference does not foreclose the possibility of preemption, where applicable. *See, e.g., Gen. Motors Corp. v. Abrams*, 897 F.2d 34, 36 (2d Cir.1990) ("While the protection of consumers from unfair practices is a traditional state police power function, federal laws and administrative regulations may operate in tandem with—or even preempt—state law under the *Supremacy Clause*. . . .").

Similarly, in *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000), the Court examined whether the National Traffic and Motor Vehicle Safety Act of 1966, and a standard promulgated under it by the Department of Transportation, preempted a state common law tort action "in which the plaintiff claims that the defendant auto manufacturer, who was in compliance with the standard, should nonetheless have equipped a 1987 automobile with airbags." *Id.* at 865, 120 S.Ct. 1913. The Court concluded that "the Act, *taken together with* FMVSS 208 [the agency-promulgated standard], pre-empts the lawsuit." *Id.* (emphasis added). Both *Medtronic* and *Geier* suggest the sort of confluence between congressional purpose and agency purpose that had previously been recognized in *Fidelity Federal Savings and Loan Association v. de la Cuesta*, 458 U.S. 141, 102 S.Ct. 3014, 73 L.Ed.2d 664 (1982):

> Federal regulations have no less pre-emptive effect than federal statutes. Where Congress has directed an administrator to exercise his discretion, his judgments are subject to judicial review only to determine whether he has exceeded his statutory authority or acted arbitrarily. *United States v. Shimer*, 367 U.S. 374, 381-82, 81 S.Ct. 1554, 6 L.Ed.2d 908 (1961). When the administrator promulgates regulations intended to pre-empt state law, the court's inquiry is similarly limited.

Id. at 153-54, 102 S.Ct. 3014; *see also Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S.

707, 713, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985) ("[S]tate laws can be pre-empted by federal regulations as well as by federal statutes."). *Medtronic* and *Geier* add to the preemption analysis by suggesting that state laws are preempted when they frustrate regulations that have been promulgated following a specific inquiry into a particular area of agency authority. Leslie C. Kendrick, *FDA's Regulation of Prescription Drug Labeling: A Role for Implied Preemption*, 62 Food & Drug L.J. 227, 240-41 (2007).

Following *Medtronic* and *Geier*, the Supreme Court examined conflict preemption in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). The Court determined that fraud-on-the-FDA claims in state tort law were preempted by the Medical Device Amendments, 21 U.S.C. § 360c, *et seq. Id.* at 348, 121 S.Ct. 1012. The Court explained that "[t]he conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* In so holding, the Court emphasized the flexibility inherent in the statutory and regulatory framework, and noted that such flexibility was necessary for the FDA to pursue "difficult (and often competing) objectives." *Id.* at 349, 121 S.Ct. 1012. The Court distinguished *Medtronic*, noting that "the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA

requirements." *Id.* at 352, 121 S.Ct. 1012. Because the "existence of these federal enactments [was] a critical element in [the plaintiffs'] case," the Court held that to allow the claims to proceed "would exert an extraneous pull on the scheme established by Congress. . . ." *Id.* at 353, 121 S.Ct. 1012. In the plaintiffs' claims against Zeneca under state consumer fraud laws, the FDCA is not as clearly a "critical element," because plaintiffs may not need to show non-compliance with the FDCA in order to prevail. However, allowing these claims to proceed would unnecessarily frustrate the FDCA's purpose and FDA regulations, as the extent of agency involvement in regulating prescription drug advertising is extensive and specific. *See* 21 C.F.R. § 202.1(e)(6)(i)-(xx) and (e)(7)(i)-(xiii); Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions; Withdrawal; Availability, 69 Fed.Reg. 6308-01 (Feb. 10, 2004) ("FDA has responsibility under the Federal Food, Drug, and Cosmetic Act (the act) for regulating advertising for prescription drugs.").

An even stronger case for preemption occurs when FDA-approved labeling is the basis for allegedly fraudulent representations made in prescription drug advertising. The essential affinity between advertising and labeling is clear in the composition of the FDCA and its associated regulations. 21 U.S.C. § 321(n) (explaining criteria for "determining whether the labeling or advertising is misleading"); 21 U.S.C. § 352(n) (requiring that all advertisements include "the formula showing quantitatively each ingredient of such drug to the extent required for labels"); *see, e.g.*, 21 C.F.R. § 202.1(a)(2)

("The order of listing of ingredients in the advertisement shall be the same as the order of listing of ingredients on the label of the product, and the information presented in the advertisement concerning the quantity of each such ingredient shall be the same as the corresponding information on the label of the product."); 21 C.F.R. § 202.1(e)(3)(ii) ("[W]hen an advertisement contains a broad claim that a drug is an antibacterial agent, the advertisement shall name a type or types of infections and microorganisms for which the drug is effective clinically as specifically as required, approved, or permitted in the drug package labeling."). Although labeling is often directed at medical practitioners, the rules that govern labeling form the basis for the advertising regulations. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed.Reg. 3922, 3961 (Jan. 24, 2006) ("The purpose of prescription drug labeling is to provide health care practitioners information necessary for safe and effective use."); Prescription Drug Advertising; Content and Format for Labeling of Human Prescription Drugs, 44 Fed.Reg. 37,434, 37,460 (June 26, 1979) ("The use of quantitative statements of safety or effectiveness is permitted in drug advertisements when the representation has been approved as part of the labeling. . . ."). Accordingly, the purpose of protecting prescription drug users in the FDCA would be frustrated if states were allowed to interpose consumer fraud laws that permitted plaintiffs to question the veracity of statements approved by the FDA.

Appendix A

Implied conflict preemption of state consumer fraud laws is required in this setting because both the FDCA and FDA regulations provide specific requirements for prescription drug advertising. Congress specifically determined that "all ... proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The high level of specificity in federal law and regulations with respect to prescription drug advertising is irreconcilable with general state laws that purport to govern all types of advertising. *See, e.g.*, 21 U.S.C. § 352(n); 21 C.F.R. § 314.81(b)(3). Accordingly, the plaintiffs' state consumer fraud claims are preempted.[12]

---

12. Plaintiffs also assert that the District Court erred in utilizing the doctrine of primary jurisdiction in dismissing their complaint because they had no opportunity to argue the applicability of primary jurisdiction to their claims. Although the plaintiffs are correct that a district court may not dismiss a complaint on grounds that the plaintiffs had no opportunity to address, see *Mortensen v. First Federal Savings and Loan Association*, 549 F.2d 884, 893 n. 18 (3d Cir.1977), invocation of primary jurisdiction was, at most, an alternative holding. Because "we [can] affirm the district court on any basis which finds support in the record," any error that may have occurred is harmless and does not require reversal. *United States v. Maker*, 751 F.2d 614, 627 (3d Cir.1984) (quoting *Bernitsky v. United States*, 620 F.2d 948, 950 (3d Cir.1980)).

Likewise, the plaintiffs' unjust enrichment claims are untenable as a result of our holding regarding the preemption of the DCFA. The unjust enrichment claims do not rest on any sounder footing than the fraud claims. Delaware defines unjust

(Cont'd)

Appendix A

IV.

Leave to Amend

The decision whether to grant leave to amend is within the discretion of the district court. *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 654 (3d Cir.1998). The Supreme Court has explained that

> In the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.—the leave sought should, as the rules require, be 'freely given.'

(Cont'd)
enrichment as "the unjust retention of a benefit to the loss of another, or the retention of money or property of another against the fundamental principles of justice or equity and good conscience." *Schock v. Nash*, 732 A.2d 217, 232 (Del.1999) (quotation omitted). Because no fraud claim exists under the DCFA due to the operation of preemption, there was no deception by Zeneca cognizable in state law and therefore no retention of money against the fundamental principles of justice at issue in this case. *See Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 943 (7th Cir.2001).

We have considered the other arguments raised, and conclude that they are without merit and compel no separate discussion.

Foman v. Davis, 371 U.S. 178, 182, 83 S.Ct. 227, 9 L.Ed.2d 222 (1962). The District Court did not rule on appellants' request for leave to amend.

The plaintiffs amended their complaint once in response to a motion to dismiss dated March 31, 2005 that advanced the same arguments presented in the motion to dismiss at issue here. Plaintiffs had an opportunity to revise their complaint in response to the renewed objections, but failed to cure the deficiencies. Additionally, although the plaintiffs suggest that some additional facts might be pled in order to cure the defects of the complaint, amendment would be futile. In particular, the plaintiffs state that they could allege that "in negotiations between the FDA and AstraZeneca regarding Nexium labeling, the FDA stated it would not approve any representations by AstraZeneca that Nexium is more effective than Prilosec, and AstraZeneca responded it would not make any such statement." This will not overcome the deficiencies in the complaint because the advertisements are not subject to state consumer fraud law, as explained in part III.

V.

The DCFA exemption for advertisements or merchandising practices which are subject to and compliant with the rules and regulations of, and the statutes administered by, the FTC, 6 Del. Code Ann. § 2513(b)(2), does not preclude the plaintiffs' suit. The language of the exemption circumscribes the federal agencies to which advertisers may look in seeking to

exclude their conduct from the prohibition of § 2513(a). The FDA is not referenced in subsection (b)(2), nor does the FDA act as a proxy for the FTC in its regulation of prescription drug advertising. We therefore decline to read that section more broadly than the Delaware General Assembly plainly drafted it.

Although the DCFA exemption does not bar the plaintiffs' suit, their state consumer fraud claims are preempted by federal law. By specifically excluding advertisements covered by 21 U.S.C. § 352(n) and the regulations promulgated thereunder from the scope of 15 U.S.C. § 52, Congress signaled its intent to give the FDA exclusive authority to regulate prescription drug advertising. The FDA has established specific regulations regarding such advertising. To allow generalized state consumer fraud laws to dictate the parameters of false and misleading advertising in the prescription drug context would pose an undue obstacle to both Congress's and the FDA's objectives in protecting the nation's prescription drug users. Accordingly, the state consumer fraud laws are preempted by the extensive federal legislative and regulatory framework. We will affirm the judgment of the District Court.

DISSENT BY: Cowen

DISSENT

Cowen, Circuit Judge, dissenting.

The majority's conclusion that the FDCA and the implementing regulations displace the Delaware Consumer Fraud Act and the consumer protection statutes of the fifty states "ignore[s] the teaching of th[e] [Supreme] Court's decisions which enjoin seeking out conflicts between state and federal regulation where none clearly exists." *Huron Portland Cement Co. v. City of Detroit, Mich.*, 362 U.S. 440, 446, 80 S.Ct. 813, 4 L.Ed.2d 852 (1960). Because the state laws do not "stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives" of the federal law, *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S.Ct. 399, 85 L.Ed. 581 (1941), I respectfully dissent.

I.

In areas of traditional state regulation, we start with "the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) ("[B]ecause the States are independent sovereigns in our federal system, [it] ha[s] long [been] presumed that Congress does not cavalierly

pre-empt state-law causes of action."). The protection of consumers against deceptive business practices is an area traditionally regulated by the States. *California v. ARC Am. Corp.*, 490 U.S. 93, 101, 109 S.Ct. 1661, 104 L.Ed.2d 86 (1989) ("Given the long history of state common-law and statutory remedies against . . . unfair business practices, it is plain that this is an area traditionally regulated by the States." (footnote omitted)); *Fla. Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146, 83 S.Ct. 1210, 10 L.Ed.2d 248 (1963) (statute to "prevent the deception of consumers" within scope of state's police powers); *Plumley v. Commonwealth of Mass.*, 155 U.S. 461, 467, 15 S.Ct. 154, 39 L.Ed. 223 (1894) (recognizing state's power to "prevent[ ] deception or fraud in the sales of property within their respective limits"). Similarly, "[t]hroughout our history the several States have exercised their police powers to protect the health and safety of their citizens." *Medtronic*, 518 U.S. at 475, 116 S.Ct. 2240. As such, a presumption against a finding of preemption clearly applies in this case. Applying the presumption against preemption and general principles of conflict preemption, I cannot agree with the majority's finding of preemption, as discussed below.

II.

A

My first point of disagreement lies with the majority's heavy reliance upon the high level of specificity in the federal regulations as a basis for a

finding of preemption. While the prescription drug advertising regulations are unquestionably detailed and extensive, it is well-established that a preemption inquiry "cannot be judged by reference to broad statements about the 'comprehensive' nature of federal regulation." *Head v. N.M. Bd. of Exam'rs in Optometry*, 374 U.S. 424, 429-30, 83 S.Ct. 1759, 10 L.Ed.2d 983 (1963) (citations omitted); *English v. Gen. Elec. Co.*, 496 U.S. 72, 87, 110 S.Ct. 2270, 110 L.Ed.2d 65 (1990) ("Ordinarily, the mere existence of a federal regulatory scheme, even one as detailed as § 210, does not by itself imply pre-emption of state remedies."); *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 718, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985) ("[I]f an agency does not speak to the question of pre-emption, we will pause before saying that the mere volume and complexity of its regulations indicate that the agency did in fact intend to pre-empt.").[13]

Despite the volume and specificity of the federal regulations, "state statutes, otherwise valid, must be upheld unless there is found 'such actual conflict between the two schemes of regulation that both cannot stand in the same area, [ ]or evidence of a congressional design to preempt the field.' " *Head*, 374 U.S. at 430, 83 S.Ct. 1759 (quoting *Fla. Lime*, 373 U.S. at 141, 83 S.Ct. 1210);

---

13. Incidentally, the assertion that the mere "volume and complexity" of agency regulations demonstrates an implicit intent to displace all state law in a particular area is a field preemption argument, *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 884, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000), which was never raised in this case.

Fla. Lime, 373 U.S. at 143, 83 S.Ct. 1210 (finding "no inevitable collision between the two schemes of regulation").[14] As discussed further below, no such actual conflict has been demonstrated or found in this case.

B.

My second point of contention is with the majority's statement, at least within the context of this case, that Congress's purpose of protecting prescription drug users would be frustrated if plaintiffs were permitted to question the veracity of statements approved by the FDA. It is undisputed that the FDA has not approved the veracity of the particular advertisements in question, and, as discussed in greater detail below, plaintiffs are

---

14. This is not an area of the law inherently requiring national uniformity and ousting all related state law. As the Supreme Court has explained, "every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law." *Hillsborough*, 471 U.S. at 719, 105 S.Ct. 2371. Thus while prescription drug advertising merits national concern, Congress has not taken drug advertising from a health and safety issue into a field of inherently national concern. *See id.* at 720-22, 105 S.Ct. 2371 (federal regulations governing collection of blood plasma do not preempt local ordinances on the same subject matter). Indeed, even the FDA has acknowledged that "regulation of drug labeling will *not* preempt all State law actions." *See Labeling Rule*, 71 Fed.Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) (emphasis added).

not attacking, directly or indirectly, the labeling approved by the FDA.[15]

The majority refers to the "essential affinity" between advertising and labeling in support of its preemption finding. Admittedly, in defining the scope and substance of certain information to be included in drug advertisements, the FDA regulations refer to the information required or permitted in the approved labeling. *See, e.g.*, 21 C.F.R. § 202.1(a)(1) (order of listing of ingredients), (e)(3)(iii) (side effects and contraindications), (e)(6)(xi) (conditions of drug use). Consequently, a state-law claim, alleging that an advertisement consistent with the approved labeling contains inadequate disclosures or warnings regarding such matters as ingredients, side effects, contraindications, and conditions of use, might indirectly

---

15. Even assuming *arguendo* that Congress wanted labeling statements approved by the FDA to be immune to attack, that federal interest would be served by preempting state law to the extent that it afforded recovery to plaintiffs attacking the labeling. Similarly, if Congress wanted advertisements approved by the FDA to be immune to attack, that federal interest would be served by preempting state law to the extent that it afforded recovery to plaintiffs attacking the advertisements. Here, plaintiffs are not attacking the labeling of Nexium. There is also no record evidence that the FDA approved the Nexium advertisements which they are challenging. Specifically, the FDA has not determined the veracity of advertisements touting Nexium's effectiveness as "compared with Prilosec" and indicating the benefits of Nexium in "efficacy in short-term healing" and "system control" in head-to-head studies with Prilosec.

present a conflict with the FDA's labeling determination. That kind of case would present a more difficult preemption question than the one presented here.

In the instant case, on the other hand, plaintiffs claim that advertisements of Nexium contain a false and misleading *drug comparison.* The labeling of a prescription drug does not contain or require a showing of a drug's superiority over other drugs on the market. Unsurprisingly, then, the FDA has not rendered an official opinion approving or disapproving a claim of superiority of Nexium over Prilosec.[16] As a result, there is no risk that a successful state-law claim, alleging that Nexium advertisements contain false and misleading drug comparisons, would conflict with the FDA's approval of the statements in the Nexium labeling.

The FDA's own prescription-drug advertising regulations demonstrate as much. The regulations categorize as false and misleading any advertisement that "[c]ontains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical

16. To be sure, the approved labeling for Nexium reproduces the results of clinical studies comparing the two treatments. According to FDA guidelines, however, the Clinical Studies section of labeling is intended to "facilitate an understanding of how to use the drug safely and effectively." Inclusion of the clinical studies are not intended to serve as an implicit agency determination about the superiority of one drug over another.

experience." 21 C.F.R. § 202.1(e)(6)(ii). Unlike the labeling-related provisions in the regulation, *see, e.g.*, 21 C.F.R. § 202.1(a)(1), (e)(3)(iii), (e)(6)(xi), the false and misleading drug comparison provision does not turn on the approved labeling, but on the existence of "substantial evidence or substantial clinical experience." 21 C.F.R. § 202.1(e)(6)(ii). The "essential affinity" between advertising and labeling, therefore, does not subsist in a claim attacking a statement of drug superiority in an advertisement.

In summary, because the FDA has not approved or disapproved the veracity of the advertising statements that plaintiffs challenge in this case, and plaintiffs' particular challenge does not question the veracity of any statements in the labeling approved by the FDA, there is no likelihood that plaintiffs' claims would conflict with the FDA's responsibility in protecting prescription drug users. As stated by the late Chief Justice Rehnquist, "merely identifying a purpose is not enough [for conflict preemption]; it must also be shown that the state law inevitably frustrates that purpose." *Jones v. Rath Packing Co.*, 430 U.S. 519, 545, 97 S.Ct. 1305, 51 L.Ed.2d 604 (1977) (Rehnquist, J., dissenting). Emphasizing that point, he noted:

> We must also be careful to distinguish those situations in which the concurrent exercise of a power by the Federal Government and the States or by the States alone may possibly lead to conflicts and those situations where conflicts will necessarily

> arise. "It is not ... a mere possibility of inconvenience in the exercise of powers, but an immediate constitutional repugnancy that can by implication alienate and extinguish a pre-existing right of (state) sovereignty."

Id. (quoting The Federalist No. 32, p. 243 (B. Wright ed. 1961)). Only if the purpose of the federal law cannot be accomplished—if its operation must be frustrated and its provisions be refused their natural effect—must the state law yield to the regulation of Congress. *Savage v. Jones*, 225 U.S. 501, 533, 32 S.Ct. 715, 56 L.Ed. 1182 (1912).

While the majority has identified the congressional purpose of protecting prescription drug users, it has not articulated how the state law must inevitably frustrate that purpose. There is certainly no "immediate constitutional repugnancy" between an extra-agency finding that a claim of drug superiority in an advertisement is false and misleading and the congressional purpose of protecting prescription drug users. *Jones*, 430 U.S. at 545, 97 S.Ct. 1305 (Rehnquist, J., dissenting) (internal quotations marks and citation omitted). As such, I cannot agree with the majority's finding of preemption on that basis.

C.

My third concern relates to the majority's finding that Congress's exclusion of prescription drug advertisements from the scope of 15 U.S.C. § 52 signals

a congressional intention to preempt state consumer fraud laws. The text of 21 U.S.C. § 352(n) only excludes coverage under 15 U.S.C. § 52 and does not purport to bar state-law tort actions. Nor does the legislative history to § 352(n) indicate a congressional purpose to supplant state-law actions. *See English*, 496 U.S. at 88, 110 S.Ct. 2270. Most importantly, the exclusion of prescription drug advertisements from coverage under the federal statute does not approach the required "clear and manifest" congressional purpose to preempt state law. *See Rice*, 331 U.S. at 230, 67 S.Ct. 1146.

D.

Fourth, I disagree that the majority's attempt to analogize this case to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001), where the Supreme Court found preemption based upon specific conflicts between certain FDA objectives and state-law fraud-on-the-agency claims and the interdependency between the state claims and FDCA requirements. In *Buckman*, the Court found that the plaintiffs' fraud-on-the-agency claims would have had the effect of deterring beneficial off-label uses, despite the FDA's objective not to regulate the practice of medicine, and would have caused a deluge of information concerning off-label uses, resulting in administrative burdens and delays. *Id.* at 350-51, 121 S.Ct. 1012. In addition, the Court found that unlike the traditional state tort claims, the fraud-on-the-agency claims existed solely by virtue of FDCA disclosure requirements, which Congress had given the FDA the exclusive responsibility

to enforce. *Id.* at 352, 121 S.Ct. 1012. For these reasons, the Court held that the plaintiffs' state-law claims were preempted. *Id.* at 353, 121 S.Ct. 1012.

Unlike the claims in *Buckman*, plaintiffs' claims here do not exist by virtue of a violation of FDCA disclosure requirements. The state consumer protection statutes at issue existed long before the federal enactments. Moreover, the majority does not identify any actual conflicts between the federal regime and the state statutes. There is, for example, no cited risk that the availability of state-law remedies would conflict with a particular federal objective or a careful balancing of interests that the federal government has achieved in policing prescription drug advertising. For these reasons, the claims in this case cannot be reasonably analogized to the claims in *Buckman*, and, thus, the majority's use of the reasoning in *Buckman* to support its preemption finding is misguided.

E.

Fifth, I disagree with the majority's finding of preemption to the extent it is based upon the presence of state-law parameters for false and misleading advertisements. As discussed below, the mere presence of state law standards would not inevitably lead to a collision with the federal regime.

As an initial matter, the majority characterizes plaintiffs' claims as both interposing state-law standards and vindicating federal requirements. Implicit in this

dual characterization is, necessarily, the recognition that the state standards and federal requirements are not inconsistent. Yet, it is well-established that the mere presence of state-law claims that *parallel* federal requirements is not sufficient to support a preemption finding. *See Medtronic*, 518 U.S. at 495, 116 S.Ct. 2240 ("The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law."); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 529, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992) ("State-law prohibitions on false statements of material fact do not create 'diverse, nonuniform, and confusing' standards. Unlike state-law obligations concerning the warning necessary to render a product 'reasonably safe,' state-law proscriptions on intentional fraud rely only on a single, uniform standard: falsity.").

On a number of occasions, the Supreme Court has upheld state laws that provide remedies parallel to the remedies provided by the federal law. *See, e.g., Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 257, 104 S.Ct. 615, 78 L.Ed.2d 443 (1984) ("Paying both federal fines and state-imposed punitive damages for the same incident would not appear to be physically impossible. Nor does exposure to punitive damages frustrate any purpose of the federal remedial scheme."); *Hayfield N. R.R. Co. v. Chi. and N.W. Transp. Co.*, 467 U.S. 622, 636, 104 S.Ct. 2610, 81 L.Ed.2d 527 (1984) ("Although it may seem unfair to allow a shipper a 'second bite at the apple' in

state condemnation proceedings ..., that second opportunity does not frustrate the purpose of the federal valuation scheme."); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484, 94 S.Ct. 1879, 40 L.Ed.2d 315 (1974) ("[T]he patent policy of encouraging invention is not disturbed by the existence of another form of incentive to invention."). As explained by the Supreme Court, "state causes of action are not pre-empted solely because they impose liability over and above that authorized by federal law." *California*, 490 U.S. at 105, 109 S.Ct. 1661; *English*, 496 U.S. at 89, 110 S.Ct. 2270 (same). *But see Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 706, 104 S.Ct. 2694, 81 L.Ed.2d 580 (1984) ("Since the Oklahoma law ... compels conduct that federal law forbids, the state ban clearly stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the federal regulatory scheme." (internal quotation marks and citation omitted)); *Franklin Nat. Bank v. New York*, 347 U.S. 373, 378, 74 S.Ct. 550, 98 L.Ed. 767 (1954) (finding a "clear conflict" between federal law, which authorized national banks to receive savings deposits but did not specifically permit—much less require—advertising by such banks, and New York law, which forbade them from using the word "savings" in their advertising or business).

The state statutory damages remedies for false and misleading advertisements would not frustrate the federal policy of protecting prescription drug consumers. The veracity of drug advertisements is essential to the protection of consumers. As stated in the legislative history to 21 U.S.C. § 352(n), "when a doctor is misled

his patient's health is endangered." S. Rep. No. 87-1744 (1962), *reprinted in* 1962 U.S.C.C.A.N. 2884, 2904. Given that there are limitations to the FDA's oversight over prescription drug advertisements—both congressionally—imposed limitations, such as the lack of authority to require preapproval, 21 U.S.C. § 352(n), and practical limitations attendant to the sheer volume of drug advertisements in the media, *see* Donna U. Vogt, *CRS Report for Congress: Direct-to-Consumer Advertising of Prescription Drugs* 20 (Congressional Research Service, The Library of Congress 2005) (noting that in 2003 alone, the FDA received 38,000 advertisements from drug sponsors)—the supplementation of state-law remedies would seem to aid the FDCA's objectives and purposes, not frustrate them.

For these reasons, I cannot agree that the mere presence of state law standards for false and misleading advertisements would present a conflict with the federal law.

F.

Of final note, Congress's failure to provide a private remedy for persons injured by false and misleading advertisements further convinces me that the state law remedies are not preempted. As the Supreme Court stated in *Silkwood*, "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." 464 U.S. at 251, 104 S.Ct. 615; *see also Bates v. Dow*

Agrosciences LLC., 544 U.S. 431, 450, 125 S.Ct. 1788, 161 L.Ed.2d 687 (2005) ("[I]t seems unlikely that Congress considered a relatively obscure provision like § 136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability.").

In addition, where the state law in question provides a long available form of compensation, it would be expected that Congress would express an intent to deprive injured parties of that compensation even more clearly. *See Bates*, 544 U.S. at 449, 125 S.Ct. 1788. Here, the long history of state consumer protection statutes in this country (which, incidentally, were modeled after and coexisted with the FTCA, the FDCA's predecessor insofar as prescription drug advertising is concerned) adds force to the basic presumption against preemption. *See id.* at 449-50, 125 S.Ct. 1788. That presumption has not been rebutted in this case.

In summary, because congressional intention to remove all judicial recourse for parties injured by deceptive business practices is far from clear, a finding of preemption is not permitted under Supreme Court precedent.

III.

Based upon the foregoing, I respectfully dissent, insofar as the majority concludes that the state claims are preempted.[17]

17. Apart from my general disagreement with the majority's preemption analysis, I also disagree with the majority's summary conclusion that the FDA's prescription drug advertising regulations preempt the plaintiffs' claims to the extent based upon false and misleading presentations and "detailing," as it is not clear that the regulations apply to those kinds of promotional activities.

APPENDIX B — MEMORANDUM OPINION OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE DATED NOVEMBER 8, 2005

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Civ. No. 05-075-SLR
(Lead Case)

PENNSYLVANIA EMPLOYEE BENEFIT TRUST FUND, on behalf of itself and all others similarly situated, JOSEPH MACKEN, and COMMISSIONER LINDA A. WATTERS,

Plaintiffs,

v.

ZENECA, INC. and ASTRAZENECA PHARMACEUTICALS, L.P.,

Defendants.

MEMORANDUM OPINION

Dated: November 8, 2005
Wilmington, Delaware

Appendix B

ROBINSON, Chief Judge

I. INTRODUCTION

On February 11, 2005, plaintiff Pennsylvania Employee Benefit Trust Fund filed a putative nationwide class action against AstraZeneca, Inc. and AstraZeneca Pharmaceuticals, L.P. (collectively called "defendants"). (D.I. 1) On April 5, 2005, Linda A. Watters[1] filed a putative nationwide class action against defendants. (Civ. No. 05-196-SLR, D.I. 1) On April 14, 2005, Joseph Macken filed a putative nationwide class action against defendants. (Civ. No. 05-220-SLR, D.I. 1) On May 27, 2005, Pennsylvania Employee Benefit Trust Fund, Linda A. Watters, Joseph Macken, AFSCME District Council 47 Health & Welfare Fund, Victoria Scofield, Janet McGrorty, Richard Tikkuri, Wisconsin Citizen Action, United Senior Action of Indiana and Carolina Fair Share (collectively called "plaintiffs") filed a consolidated class action complaint. (Civ. No. 05-75-SLR, D.I. 20, 27)[2] Before the court is defendants' motion to dismiss for failure to state a claim upon which relief can be granted. (D.I. 32) The court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a). (D.I. 1 at ¶ 18)

---

1. More specifically, Ms. Watters filed suit in her capacity as Commissioner, Offices of Financial Services for the State of Michigan in her capacity as Rehabilitator of The Wellness Plan and in her capacity as Liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known as OmniCare Health Plan, Inc.

2. Unless otherwise noted, all references to "D.I." are to docket items in Civ. No. 05-75-SLR, the lead case in this consolidated action.

Appendix B

II. BACKGROUND

According to the consolidated complaint (D.I. 20), the drug Prilosec is a proton-pump inhibitor ("PPI") used to treat heartburn and esophageal erosions. *Id.* By the year 2000, Prilosec, long advertised as the "purple pill", was the most widely prescribed drug in the world. *Id.* Before the patent on Prilosec expired, defendants received approval by the Food and Drug Administration ("FDA") for a new PPI, marketed as Nexium. (D.I. 20 at ¶ 6) The FDA released the approved labeling for Nexium in February 2001. (D.I. 34, ex. 1) By 2003, sales of Nexium reached $3.3 billion. (D.I. 20 at ¶ 13)

Plaintiffs allege that, once Prilosec could be sold as the generic drug omeprazole, defendants engaged in a massive advertising campaign to boost the sales of the more expensive prescription drug Nexium. In their advertisements, defendants "either implicitly or expressly represented" that Nexium was superior to Prilosec. In doing so, defendants "suppress[ed] and/or omitt[ed]" information demonstrating that "Nexium . . . [is] not more effective **at equivalent doses** to the standard therapeutic dose of Prilosec." (D.I. 20 at 155(d)) (emphasis added) Plaintiffs assert that this misleading advertising campaign has resulted in "billions of dollars of unnecessary drug expenditures by third party payors" and that "hundreds of thousands of patients have taken Nexium and continue to do so when they should not." (D.I. 20 at ¶¶ 7, 9, 11, 86, 91, 98, 110, 155, 160) Plaintiffs contend that defendants' marketing strategy has violated the Delaware Consumer Fraud Act, 6 Del. C. § 2511,

et seq ("DCFA"), as well as the consumer protection statutes of the other 49 states. (D.I. 20 ¶ 166) Plaintiffs also assert a claim for unjust enrichment and a claim of negligent misrepresentation. (D.I. 20 ¶¶ 173-78, 179-84)

III. STANDARD OF REVIEW

In analyzing a motion to dismiss pursuant to Rule 12(b)(6), the court must accept as true all material allegations of the complaint and it must construe the complaint in favor of the plaintiffs. *See Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc.*, 140 F.3d 478, 483 (3d Cir. 1998). "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." *Id.* Claims may be dismissed pursuant to a Rule 12(b)(6) motion only if the plaintiffs cannot demonstrate any set of facts that would entitle them to relief. *See Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). The moving party has the burden of persuasion. *See Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991).

IV. DISCUSSION

In order to prevail on their theory of liability, plaintiffs must demonstrate, first, that the Nexium advertisements "either implicitly or expressly" describe Nexium as superior to Prilosec and, second, that Nexium, in fact, is "not more effective at equivalent doses to the

standard therapeutic dose of Prilosec." The question before the court instantly is whether it has jurisdiction to resolve these issues as pled. For the reasons that follow, the court concludes that plaintiffs have not stated claims upon which relief can be granted.

A. Misleading Advertising Under the DCFA

With respect to the first issue, the DCFA provides that

> [t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether or not any person has in fact been misled, deceived or damaged thereby, is an unlawful practice.

6 Del. C. § 2513(a). The purpose of the DCFA is to "protect consumers and legitimate business enterprises from unfair or deceptive merchandising practices." 6 Del. C. § 2515.[3] Despite its broad purpose, however,

3. Plaintiffs use statements made in defendants' 2000 Annual Report as evidence of false or misleading statements. The case law provides that the court "cannot ignore the clear language of the statute which restricts its application to deceptive practices 'in connection with the sale or advertisement' of

(Cont'd)

the DCFA does not apply "[t]o any advertisement or merchandising practice which is subject to and complies with the rules and regulations, of and the statutes administered by, the Federal Trade Commission." 6 Del. C. § 2513(b)(2). The Federal Trade Commission ("FTC") and the FDA share exclusive jurisdiction over regulation of drug marketing; the FDA is given primary authority to regulate prescription drugs. 36 Fed. Reg. 18,539 (1971) ("The Food and Drug Administration has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising."). The information included in the labeling of a new drug reflects a determination by the FDA that the information is not "false or misleading." 21 C.F.R. § 314.125(b)(6) (stating the FDA must deny a new drug application if it determines that "[t]he proposed labeling is false or misleading in any particular"). By approving information to be included in the drug labeling, the FDA has determined that the information complies with its rules and regulations. Therefore, if the FDA labeling supports the statements made in advertising for an FDA-approved drug, the statements are not actionable under 6 Del. C. § 2513(b). *American Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135 (S.D.N.Y. 1987) ("Moreover, AHP's compliance with FDA labeling standards automatically puts it in compliance with FTC requirements as well, since the FTC has officially

---

(Cont'd)

merchandise.'" *Norman Gershman's v. Mercedes-Benz*, 558 A.2d 1066, 1074 (Del. Super. 1989). Plaintiffs have not alleged that any statements used in the Annual Report were used in the sale or advertisement of Nexium to consumers.

recognized that the FDA has primary jurisdiction over all matters relating to the labeling of [over the counter] drugs.") (internal citations omitted); *Bober v. Glaxo Wellcom PLC*, 246 F.3d 934, 942 (7th Cir. 2001) ("[R]ecognizing the primacy of federal law in this field, the Illinois statute itself protects companies from liability if their actions are authorized by federal law."); *see Solvay Pharmaceuticals, Inc. v. Ethex Corp.*, 2004 WL 742033 (D. Minn. 2004) ("[W]here a claim requires interpretation of a matter that is exclusively within the jurisdiction and expertise of the FDA and FDCA, plaintiffs cannot use the Lanham Act as a backdoor to private enforcement.") (citing *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990)).

Plaintiffs have characterized as misleading multiple statements found in the Nexium advertisements. These statements will be addressed in seriatim.

1. **Nexium is a "new" drug**. Defendants received FDA approval for a "new PPI". (D.I. 20 at ¶ 6)

2. **"The Purple Pill"**. The FDA-approved labeling describes the pill as "amethyst" in color. (D.I. 34, ex. 1 at 39)

3. **"From the makers of Prilosec"**. Nexium is manufactured for AstraZeneca, as was Prilosec. (D.I. 34, ex. 1 at 40)

Appendix B

4. **"Compared with Prilosec"**. Nexium was compared to Prilosec in the FDA approved labeling. (D.I. 34, ex. 1 at 13)

5. **"Just one prescription Nexium a day gives may people complete resolution of heartburn symptoms"**. The FDA-approved labeling describes studies where "many" patients were symptom-free of heartburn with the use of Nexium. (D.I. 34, ex l at 14, 18) The labeling states:

> Two multicenter, randomized, double-blind placebo-controlled studies were conducted in a total of 717 patients comparing four weeks of treatment with NEXIUM 20 mg or 40 mg once daily versus placebo for resolution of GERD symptoms. . . . The percentage of patients that were symptom-free of heartburn was significantly higher in the NEXIUM groups compared to placebo at all follow-up visits.

(D.I. 34, ex. 1 at 18) In addition, the labeling contains a chart of the Cumulative Percent with Sustained Resolution (defined as the cumulative proportion of patients who have reached the start of sustained resolution). After 14 days, the three studies resulted in 64.8%, 65.4%, and 67.6% (patients who reached the start of sustained resolution), respectively. After 28 days, the values were 74.2%, 73.9%, 75.1%. (D.I. 34, ex. 1 at 14) While the court need not define "many," it concludes these numbers are sufficient to support the statement made in the advertisement.

6. **"Proven efficacy in short-term healing (4-8 weeks)"**. The FDA-approved labeling states that Nexium "is indicated for the short-term treatment (4 to 8 weeks) in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis." (D.I. 34, ex. 1 at 23) In addition, the labeling recommends 40 mg of Nexium once daily for 4 to 8 weeks for the healing of erosive esophagitis. (D.I. 34, ex. 1 at 37)

7. **"Proven symptom control"**. The FDA-approved labeling describes studies where "the proportion of patients on Nexium who remained in remission and were free of heartburn and other GERD symptoms was well differentiated from placebo." (D.I. 34, ex. 1 at 18) Furthermore, the labeling concludes that, in a study done, "[t]he percentage of patients that were symptom-free of heartburn was significantly higher in the NEXIUM groups compared to placebo at all follow-up visits." (D.I. 34, ex. 1 at 18)

8. **"Heal the damage"**. The FDA-approved labeling indicates Nexium is effective in the "healing and symptomatic resolution" of erosive esophagitis. (D.I. 34, ex. 1 at 14, 18, 23, 34)

9. **"In GERD patients, power to control acid"**. The FDA-approved labeling includes a study done to determine the pH in patients with symptomatic gastroesophageal reflux disease (GERD). The data for Nexium 40 mg showed the pH remained above 4 for 16.8

hours.[4] (D.I. 34, ex. 1 at 7) With Nexium 20 mg, the pH remained above 4 for 12.7 hours.

Plaintiffs take issue with this statement because, according to plaintiffs, the FDA reviewers do not believe that PPIs are effective for GERD patients in general. Nevertheless, Nexium was FDA-approved for treatment of GERD. (D.I. 34, ex. 1 at 37)

10. **"Safety and tolerability similar to Prilosec"**. The FDA-approved labeling describes a study wherein the "safety in the treatment of healing erosive esophagitis" was conducted on patients taking Nexium 20 mg, Nexium 40 mg, omeprazole (Prilosec) 20 mg daily. "The most frequently occurring adverse events . . . in all three groups was headache (5.5, 5.0 and 3.8, respectively) and diarrhea (no difference among the three groups). Nausea, flatulence, abdominal pain, constipation, and dry mouth occurred at similar rates among patients taking Nexium or omeprazole." (D.I. 34, ex. 1 at 32)

Having reviewed all the advertising materials cited by plaintiffs, the court concludes that such materials are related to the safety and efficacy of Nexium, are consistent with the FDA-approved labeling and, therefore, are not actionable under the DCFA pursuant to 6 Del. C. § 2513(b)(2).

---

4. A higher pH results in a less acidic environment.

Alternatively, the court concludes that, even if the DCFA exception were held not to apply to the statements made in the Nexium advertisements, any statements made that comply with the FDA-approved labeling would not be actionable under a state consumer fraud act because they are preempted by federal law.

The information included in the labeling of a new drug reflects a determination by the FDA that the information is not "false or misleading." 21 C.F.R. § 314.125(b)(6). *See Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F.Supp.2d 296, 301 (S.D.N.Y. 1998) (granting a motion to dismiss because the challenged statements "comport substantively," even if not "precisely," with the FDA-approved labeling and can be considered "neither false nor misleading"); *SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 1996 WL 280810, *13 (S.D.N.Y. 1996) (concluding that in a Lanham Act case, the advertisements were "neither facially false nor misleading" because the claims challenged were "based on the package labeling approved by the FDA"); *American Home Products*, 672 F.Supp. at 144 (holding that "compliance with FDA warning requirements" is a complete defense to Lanham Act and unfair competition claims). For this reason, the claims of violation of the deceptive practices and consumer fraud acts of the fifty states are dismissed. To the extent that any of these statutes do not have a similar exemption clause, the claims are preempted by the FDA's approved labeling.

Appendix B

B. Nexium's Efficacy

Plaintiffs claim that Nexium advertisements "either implicitly or expressly represent[]" that Nexium is superior to Prilosec "at equivalent doses." As a preliminary matter, in its review of the advertising materials of record, the court did not find any explicit statements that Nexium was "superior" to Prilosec.[5] Even if any of the advertisements were deemed to implicitly claim that Nexium is superior to Prilosec, the court concludes that such claims, if consistent with the FDA-approved labeling, related to the safety or efficacy of the drug and are excluded from liability under the DCFA.[6]

---

5. The following statements mention Prilosec: **"We captured the essence of Prilosec ... and created a new PPI ... Introducing Nexium"**. Nexium has been approved by the FDA as a "new PPI". Since both Prilosec and Nexium are PPIs, the court does not find the language "We captured the essence of Prilosec" as inconsistent with the FDA-approved labeling or as touting the superiority of Nexium over Prilosec. **"In erosive esophagitis sutdies compared with Prilosec"**. As detailed above, Nexium was compared with Prilosec in studies. The advertisement does not comment on the results of the comparisons. Moreover, it is important to note that any comparisons made in the studies between omeprazole 20 mg (Prilosec) and Nexium 40 mg cannot be deemed misleading, as a 40 mg omeprazole (Prilosec) has not been approved by the FDA.

6. Plaintiffs cite to an FDA reviewer who specifically looked at whether Nexium performed better than Prilosec. The court finds this is evidence that superiority is something the FDA considers in its labeling determinations. Therefore, claims of superiority do fall under the categories of safety and efficacy.

Alternatively, in order to prevail on a claim that such an advertisement is false or misleading, plaintiffs would have the burden to prove the fact that the approved dosage of Nexium is not superior to the approved dosage of omeprazole/Prilosec. The issue of whether one drug is more effective than another drug is clearly within the expertise of the FDA and should not be resolved in a court of law through the adversarial system. The court concludes, therefore, that plaintiffs have not stated a claim upon which relief can be granted by this court. *See Generally Sandoz*, 902 F.2d at 230-32 (declining to decide whether a label is literally false when the FDA had yet to so determine).

C. Unjust Enrichment

"The elements of unjust enrichment are (1) an enrichment; (2) an impoverishment; (3) a relation between the enrichment and impoverishment; (4) the absence of justification; and (5) the absence of a remedy at law." *Jackson Nat'l. Live Ins. Co. v. Kennedy*, 741 A.2d 377, 393 (Del. Ch. 1999). Plaintiffs have not pled a relationship between the alleged enrichment and the alleged impoverishment, as they have not specifically pled that they relied on the defendants' advertisements in purchasing Nexium. Furthermore, plaintiffs have not sufficiently pled an absence of justification by defendants regarding the advertisements. Indeed, the only foreseeable way to show an absence of justification is to show the misrepresentations are not true (i.e., that Nexium is not superior to Prilosec). As stated above, the court declines to entertain this argument.

D. Negligent Misrepresentation

For a claim of negligent misrepresentation, plaintiffs must allege: "(1) a pecuniary duty to provide accurate information, (2) the supplying of false information, (3) failure to exercise reasonable care in obtaining or communicating information, and (4) a pecuniary loss caused by justifiable reliance upon false information ." *HMG/Courtland Properties, Inc. v. Gray*, 1999 WL 504781, at *24 (Del. Ch. 1995) Plaintiffs have not alleged a justifiable reliance by each of the named plaintiffs in the suit and, thus, the claim for negligent misrepresentation is dismissed.

V. CONCLUSION

For the reasons stated herein, defendants' motion to dismiss is granted. An appropriate order shall issue.

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT DENYING PETITION FOR REHEARING FILED AUGUST 17, 2007

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Case No.: 05-5340

PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND on behalf of itself and all others similarly situated; JOSEPH MACKEN; COMMISSIONER LINDA A. WATTERS,

Appellants

v.

ZENECA INC; ASTRAZENECA PHARMACEUTICALS LP;

SUR PETITION FOR REHEARING

Present: SCIRICA, *Chief Judge*, SLOVITER, McKEE, AMBRO, FUENTES, SMITH, FISHER, CHAGARES, JORDAN, HARDIMAN, COWEN, and SILER, *Circuit Judges**

The petition for rehearing filed by appellants in the above-entitled case having been submitted to the judges who participated in the decision of this Court and to all

* The votes of the Honorable Robert E. Cowen and the Honorable Eugene E. Siler, Jr., Senior United States Circuit Judges, are limited to panel rehearing.

the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular service not having voted for rehearing, the petition for rehearing by the panel and the Court en banc, is denied. Senior Judge Cowen votes for panel rehearing for the reasons set forth in his dissenting opinion. Judge Ambro, Fisher, and Jordan would grant rehearing by the court en banc.

BY THE COURT,

/s/ D. Brooks Smith
Circuit Judge

Dated: September 19, 2007

APPENDIX D — STATUTES AND CONSTITUTIONAL PROVISION INVOLVED

21 USCS § 337

§ 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has,

within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

21 USCS § 352

§ 352. Misbranded drugs and devices

* * *

(n) Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances. In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true

statement of (1) the established name as defined in paragraph (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under paragraph (e) of this section, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 371(e) of this title, except that (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 52 to 57 of Title 15. This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers.

* * * *

Appendix D

PUBLIC LAW 87-781-OCT. 10, 1962

Public Law 87-781

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, effectiveness, and reliability of drugs, authorize standardization of drug names, and clarify and strengthen existing inspection authority; and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act, divided into titles and sections according to the following table of contents, may be cited as the "Drug Amendments of 1962".

* * *

TITLE II—FACTORY INSPECTION AND EFFECT ON STATE LAWS

* * *

EFFECT ON STATE LAWS

Sec. 202. Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.

* * * *

Appendix D

U.S. Const. Art. VI, cl. 2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

86

(2)

No. 07-822

FILED
FEB 21 2008
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, ET AL.,

Petitioners,

v.

ZENECA, INC. ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF IN OPPOSITION

JACK B. BLUMENFELD
R. JUDSON SCAGGS, JR.
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 North Market Street
P. O. Box 1347
Wilmington, DE 19899
(302) 658-9200

MARK E. HADDAD*
DAVID R. CARPENTER
SIDLEY AUSTIN LLP
555 West Fifth Street, Suite 4000
Los Angeles, CA 90013
(213) 896-6000

ROBERT N. HOCHMAN
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, Illinois 60603
(312) 853-7036

Counsel for Respondents

February 21, 2008 * Counsel of Record

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

QUESTION PRESENTED

Whether the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and Food and Drug Administration ("FDA") regulations preempt state law false advertising claims when the marketing challenged in the complaint is based on FDA-approved labeling of a prescription drug.

PARTIES TO THE PROCEEDING

Petitioners Pennsylvania Employees Benefit Trust Fund ("PEBTF"), Joseph Macken, and Commissioner Linda A. Watters were plaintiffs in the district court and appellants in the court of appeals.

Respondents Zeneca Inc. and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca")* were defendants in the district court and appellees in the Court of Appeals.

The petition's List of Parties to the Proceeding also identifies, as petitioners, AFSCME District Council AFSCME District Council 47 Health & Welfare Fund, Victoria Scofield, Janet McGrorty, Richard Tikkuri, Wisconsin Citizen Action, United Senior Action of Indiana, and North Carolina Fair Share. These parties were plaintiffs in the district court but failed to file a notice of appeal and were not included in the Notice of Appeal filed by PEBTF, Macken, and Watters. Accordingly, in the court of appeals, AstraZeneca moved pursuant Federal Rule of Appellate Procedure 3(c) to dismiss the appeal as to the seven non-appealing plaintiffs. The court of appeals denied the motion as moot due to the court's affirmance of the judgment. See Pet. App. 3a n.2. Nonetheless, because the failure to file a notice of appeal is jurisdictional, see *Airline Pilots Ass'n* v. *Cont'l Airlines (In re Cont'l Airlines)*, 125 F.3d 120, 128-29 (3d Cir. 1997) (citing *Torres* v. *Oakland*

---

* Pursuant to Rule 29.6, respondents hereby state that AstraZeneca Pharmaceuticals LP and Zeneca Inc. are wholly-owned subsidiaries of AstraZeneca PLC. American Depository Receipts of AstraZeneca PLC are available on the New York Stock Exchange; no other publicly held corporation owns 10 percent or more of the stock of Zeneca Inc. or of AstraZeneca Pharmaceuticals LP.

Scavenger Co., 487 U.S. 312, 320-21 (1988)), AstraZeneca maintains that these entities are not parties in this Court.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDING	ii
TABLE OF AUTHORITIES	iv
BRIEF IN OPPOSITION	1
COUNTERSTATEMENT OF THE CASE	3
REASONS FOR DENYING THE PETITION	14
CONCLUSION	32

TABLE OF AUTHORITIES

CASES Page

Airline Pilots Ass'n v. *Cont'l Airlines*, 125 F.3d 120, (3d Cir. 1997) ..... ii, iii
Alpharma, Inc. v. *Pennfield Oil Co.*, 411 F.3d 934 (8th Cir. 2005) 30
Bates v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005) 24
Bell Atl. Corp. v. *Twombly*, 127 S. Ct. 1955 (2007) 22
Bober v. *Glaxo Wellcome PLC*, 246 F.3d 934 (7th Cir. 2001) 28
Buckman Co. v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) 23
Crosby v. *Nat'l Foreign Trade Council*, 530 U.S. 363 (2000) 16
Fidelity Fed. Sav. & Loan Ass'n v. *de la Cuesta*, 458 U.S. 141 (1982) 17, 23
Geier v. *American Honda Motor Co.*, 529 U.S. 861 (2000) 23, 24, 27
Hillsborough County v. *Automated Med. Labs., Inc.*, 471 U.S. 707 (1985) 16, 26
Louisiana Public Service Commission v. *FCC*, 476 U.S. 355 (1986) 23
Levine v. *Wyeth*, ___ A.2d ___, 2006 WL 3041078 (Vt. Oct. 27, 2006) 28, 29
N.J. Citizen Action v. *Schering-Plough Corp.*, 842 A.2d 174 (N.J. Super. Ct. App. Div. 2003) 28
Perez v. *Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. 1999) 29, 30
Prohias v. *AstraZeneca Pharms., L.P.*, 958 So. 2d 1054 (Fla. Dist. Ct. App.), *review denied*, 969 So. 2d 1014 (Fla. Nov. 7, 2007) 27

TABLE OF AUTHORITIES—continued

Page

In re Warfarin Sodium Antitrust Litg., 391 F.3d 516 (3d Cir. 2004) 30
Warner-Lambert Co. v. *Kent*, No. 06-1498 (set for argument Feb. 25, 2008) 29
Weinberger v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973) 3, 17
Wyeth v. *Levine*, 76 U.S.L.W. 3391 (Jan. 18, 2008) (No. 06-1249) 28

STATUTES AND REGULATIONS

Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 26
Food and Drug Administration Amendents Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 ..... 5, 6
21 U.S.C. § 301 *et seq.* 3
§ 332 5
§ 333 5
§ 336 26
§ 352(n) 4, 6, 17, 24
§ 355 ..... 1, 3, 4, 17
§ 393(b) 3
Del. Code, tit. 6, § 2511 *et seq.* 11
Del. Code, tit. 6, § 2513(b) 12
Fla. Stat. § 501.212(1) 27
21 C.F.R. § 10.30 26
§ 10.65(a) 21
§ 10.85(k) 21
§ 201.56 ..... 4, 6, 18
§ 201.57 4
§ 201.80 4
§ 202.1 ..... *passim*
§ 314.50(c)(2)(i) 4

TABLE OF AUTHORITIES—continued

Page

21 C.F.R. § 314.70(c) 28
§ 314.81(b)(3)(i) 6
§ 314.105(c) 4
§ 314.125(b) 3, 4, 17
§ 314.126 3
Prescription Drug Advertising: Content and Format for Labeling of Human Prescription Drugs, 44 Fed. Reg. 37,434 (June 26, 1979) 6
Direct-to-Consumer Promotion, 60 Fed. Reg. 42,581 (Aug. 16, 1995) 5
Professional Product Labeling, 60 Fed. Reg. 52,196 (Oct. 5, 1995) 4, 6, 17, 21, 22
Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997) 24
Consumer-Directed Promotion of Regulated Medical Products, 70 Fed. Reg. 54,054 (Sept. 13, 2005) 7
Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) 4, 6, 18, 21, 22

SCHOLALRY AUTHORITY

Thomas A. Hayes, *Drug Labeling and Promotion*, 51 Food & Drug L.J. 57 (1996) 5, 6

OTHER AUTHORITIES

Warning Letter to John C. Martin, Gilead Sciences, Inc. (July 29, 2003), *at* http://www.fda.gov/foi/warning_letters/archive/g4180d.pdf 24

TABLE OF AUTHORITIES—continued

Page

Statement of Janet Woodcock Before the Senate Special Committee on Aging, 2003 WL 21701807 (July 22, 2003) 5

FDA, *Guidance for Industry: Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products – Content and Format* (Jan. 2006), *available at* http://www.fda.gov/CDER/GUIDANCE/5534fnl.pdf..... 22

FDA, *Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products* (Feb. 2000), *available at* http://www.fda.gov/cder/guidance/2125fnl.pdf..... 5

FDA, Nexium Label (2001), *at* http://www.fda.gov/cder/foi/label/2001/21153lbl.pdf..... 7, 8, 20

FDA, Prilosec Label (2007), *at* http://www.fda.gov/cder/foi/label/2007/019810s085lbl.pdf..... 8

FDA, DDMAC, *Frequently Asked Questions* (Nov. 7, 2006), *at* http://www.fda.gov/cder/ddmac/faqs.htm#new..... 20

IN THE

Supreme Court of the United States

No. 07-822

PENNSYLVANIA BENEFIT EMPLOYEES TRUST FUND, ET AL.,

Petitioners,

v.

ZENECA, INC., ET AL.

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF IN OPPOSITION

Respondents Zeneca Inc. and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca") respectfully oppose the petition for writ of certiorari.

The conflict preemption principles that dispose of petitioners' claims are uncontroversial and even undisputed. Federal law preempts state law false advertising claims that challenge the promotion of a prescription drug based on FDA-approved labeling. Such preemption flows inevitably from the federal statutory and regulatory process for approving prescription drugs. Approval of labeling is an essential element of new drug approval, and FDA shall not approve labeling that is "false or misleading in any particular." 21 U.S.C. § 355(d). Once approved,

labeling serves as the basis for drug promotion. Any state law that makes it unlawful for manufacturers to promote drugs based on labeling that FDA has already determined is neither false nor misleading directly conflicts with and obstructs the federal scheme.

This is the basis on which the district court dismissed petitioners' Consolidated Class Action Complaint ("Complaint"). The district court held that petitioners' claims were preempted because all of the challenged promotional activity is supported by FDA-approved labeling. No decision of this or any other court conflicts with the preemption principle that the district court applied.

This legal principle is so straightforward that even petitioners have not challenged it. They have claimed that their Complaint challenges conduct beyond what the labeling supports. But that assertion raises a purely case-specific dispute about the breadth of their Complaint that does not warrant this Court's review. Furthermore, their assertion is belied by a simple comparison of the Complaint with the labeling. That comparison confirms that this Court's review would not extend beyond the straightforward rule of conflict preemption that petitioners do not dispute.

Petitioners also argue that the court of appeals affirmed the district court's judgment on a broader ground of field preemption, one that would render all state law false advertising claims preempted regardless of their relationship to FDA-approved labeling. That is neither what the court of appeals said it held nor what it needed to hold in order to affirm the judgment. Petitioners' broad reading of the opinion is in any event not in conflict with, and indeed has never even been addressed by, any other court. Thus, that broad reading would not merit this

Court's review even if the Court were likely to reach it, which it is not.

COUNTERSTATEMENT OF THE CASE

1. *Regulatory background.* Congress has regulated prescription drugs since 1906 with the Federal Food and Drugs Act and continuing through the present with the modern Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* Congress has designated FDA as the "expert agency" for carrying out the FDCA's purposes and ensuring the safe and effective use of prescription drugs. *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973). FDA's mission includes "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products." 21 U.S.C. § 393(b)(1).

In connection with this mission, FDA has exclusive jurisdiction to evaluate a "new drug application" ("NDA"), the approval of which is necessary to market a drug in the United States. See *id.* § 355(a),(b); see also *Hynson*, 412 U.S. at 627. An NDA must include, among other information, (1) the clinical studies and reports showing that a drug is "safe" and "effective" for its proposed uses,[1] and (2) the proposed labeling (or "package insert"), which describes the drug's pharmacology and sets forth its uses and indications, approved dosage, adverse

---

[1] See 21 U.S.C. § 355(b) (requiring that NDA include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use"); 21 C.F.R. §§ 314.125(b)(2)-(5), 314.126.

events, and contraindications.[2] FDA reviews these materials and will approve an NDA only "after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling." 21 C.F.R. § 314.105(c). FDA shall not approve a drug if there "is a lack of substantial evidence that the drug product will have the effect it purports or is represented to have," or if its labeling is "false or misleading in any particular." 21 U.S.C. § 355(d); 21 C.F.R. § 314.125(b)(5),(6).

A prescription drug's labeling "communicates the conclusions of FDA review of the data" in the NDA and provides a key source for informing health care practitioners about the drug. Professional Product Labeling, 60 Fed. Reg. 52,196, 52,196 (Oct. 5, 1995). FDA "carefully controls the content of prescription drug labeling" to ensure that it "reflects thorough FDA review of the pertinent scientific evidence" and presents "the agency's formal, authoritative conclusions" about the drug's safe and effective use. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3968 (Jan. 24, 2006) ("Labeling Rule").

In recognition of FDA's expertise and its unique capacity to evaluate the accuracy of information presented to the public regarding prescription drugs, Congress has granted FDA the power to regulate prescription drug advertising. 21 U.S.C. § 352(n). Since 1985, FDA has permitted the promotion of prescription drugs not only to physicians but also

---

[2] See 21 U.S.C. § 355(b); 21 C.F.R. § 314.50(c)(2)(i); see also 21 C.F.R. §§ 201.56-.57 (providing general and specific requirements, respectively, for prescription-drug labeling); *id.* § 201.80 (same for older drugs not subject to § 201.57).

directly to consumers. Direct-to-Consumer Promotion, 60 Fed. Reg. 42,581, 42,581-82 (Aug. 16, 1995).

FDA has adopted extensive and highly specific regulations to fulfill its obligation to prevent false or misleading prescription-drug advertising. See 21 C.F.R. § 202.1. FDA strictly regulates such activity through its Division of Drug Marketing, Advertising, and Communications ("DDMAC"), which oversees a "comprehensive surveillance, enforcement and education program." *Statement of Janet Woodcock Before the Senate Special Committee on Aging*, 2003 WL 21701807 (July 22, 2003). FDA's broad enforcement power includes the authority to seek injunctions, consent decrees, and seizures, to issue warning letters, and to make referrals for criminal prosecution. See 21 U.S.C. §§ 332, 333; see also Woodcock Statement, 2003 WL 21701807; Thomas A. Hayes, Drug Labeling and Promotion, 51 Food & Drug L.J. 57, 57-58 (1996). Congress recently heightened that power with the Food and Drug Administration Amendments Act of 2007 ("FDAAA"),[3] which, *inter alia*, authorizes the administrative imposition of civil monetary penalties for the dissemination of false or misleading DTC advertising. FDAAA § 901(d)(4), 121 Stat. at 940 (amending 21 U.S.C. § 333).

FDA also reviews advertising and promotional materials prior to approval and launch of any drug[4] and, post-launch, has required manufacturers to submit promotional labeling and advertising to

---

[3] Pub. L. No. 110-85, 121 Stat. 823.

[4] See FDA, *Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products* 7 (Feb. 2000), http://www.fda.gov/cder/guidance/2125fnl.pdf.

DDMAC at the time of first use. 21 C.F.R. § 314.81(b)(3)(i). Under FDAAA, FDA now has the authority to require manufacturers to submit any prescription-drug television advertisement for review 45 days prior to its dissemination. See FDAAA § 901(d)(2), 121 Stat. at 939 (adding 21 U.S.C. § 353b).

The regulatory standards that ensure accuracy in information disseminated to the public through both labeling and advertising are intrinsically linked. See, *e.g.*, 21 U.S.C. § 352(n); 21 C.F.R. § 202.1(e)(3)(ii), (4), (6). Labeling "also serves as a basis for product promotion," and FDA regulations permit manufacturers to market approved drugs in accordance with FDA-approved labeling. Professional Product Labeling, 60 Fed. Reg. at 52,196 (explaining that a drug's advertising generally must "be consistent with its approved labeling"); see also 21 C.F.R. § 202.1(e); Labeling Rule, 71 Fed. Reg. at 3961 ("[Labeling] is often used to provide information for [DTC] advertisements."); Prescription Drug Advertising; Content and Format for Labeling of Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,460 (June 26, 1979). For example, advertising claims about safety and efficacy, including comparisons to other drugs, must be based on what is "approved or permitted for use in labeling," or supported "by substantial evidence or substantial clinical experience," 21 C.F.R. § 202.1(e)(6)(i), just as "substantial evidence" must support claims in the labeling, *id.* § 201.56(a)(3). See also Hayes, *supra*, at 63.

In short, FDA labeling and advertising regulations operate together toward a common overarching goal: "to ensure that the promotion of medical products directed to professionals and consumers is truthful,

not misleading, and contains balanced risk and benefit information." Consumer-Directed Promotion of Regulated Medical Products, 70 Fed. Reg. 54,054, 54,056 (Sept. 13, 2005).

2. *Regulatory approval of Nexium.* Respondent AstraZeneca manufactures NEXIUM® (esomeprazole magnesium), which is one in a class of drugs called proton-pump inhibitors ("PPIs"). PPIs inhibit the production of stomach acid and are generally used to treat gastroesophageal reflux disease ("GERD" or "acid reflux disease"), which manifests in frequent heartburn, and erosive esophagitis ("EE"), which is damage to the lining of the esophagus. When, in February 2001, FDA issued its final approval to market Nexium, the final labeling stated it had been approved for three GERD-related indications: (1) healing of EE, (2) maintenance of healing EE, and (3) treatment of symptomatic GERD ("s-GERD"). See FDA, Nexium Label 24 (as approved Feb. 20 2001), http://www.fda.gov/cder/foi/label/2001/21153lbl.pdf ("Nexium Labeling").[5] AstraZeneca also manufactures and sells PRILOSEC® (omeprazole), which was the pioneer PPI.

Nexium's labeling summarizes the clinical studies used to obtain FDA approval. See Nexium Labeling at 10-15. For efficacy in treating EE, Nexium was tested at different doses—40 mg and 20 mg—and compared with omeprazole (Prilosec) at its maximum approved dose of 20 mg for EE healing. *Id.* at 10-11. AstraZeneca had similarly tested Prilosec at 40 mg and 20 mg doses for EE when seeking approval to

---

[5] The FDA-approved labeling for both Nexium and Prilosec were placed before the district court (and similarly considered by the court of appeals) on an unopposed request for judicial notice.

market Prilosec, but FDA found that the "40 mg dose was not superior to the 20 mg dose of PRILOSEC in the percentage healing rate." FDA, Prilosec Label 11, http://www.fda.gov/cder/foi/label/2007/019810s085lbl.pdf ("Prilosec Labeling").

With Nexium, however, FDA reached a different conclusion. As Nexium's FDA-approved labeling shows, in all three clinical trials comparing Nexium 40 mg to omeprazole 20 mg, Nexium 40 mg showed higher rates of healing EE, and in two of these trials the increased rate was statistically significant. Nexium Labeling 10. The labeling also summarizes data showing that Nexium 40 mg provided statistically significant, increased rates of sustained symptom resolution for EE patients as compared to omeprazole 20 mg. *Id.* at 11. Nexium 40 mg also demonstrated faster resolution of symptoms for EE patients, as the labeling states: "In these four studies, the range of median days to the start of sustained resolution (defined as 7 consecutive days with no heartburn) was 5 days for NEXIUM 40 mg, 7-8 days for NEXIUM 20 mg and 7-9 days for omeprazole 20 mg." *Id.* Accordingly, the labeling reflects that FDA approved Nexium at doses of 20 mg or 40 mg once daily (for 4 to 8 weeks) for the healing of EE. Nexium Labeling 24.[6]

3. *Petitioners' claims.* The Complaint acknowledges both that the studies showed Nexium 40 mg has advantages over Prilosec 20 mg, and that FDA relied upon these studies in approving Nexium. Supp. App. 11-13 (Compl. ¶¶ 50, 58). Nonetheless, the Complaint asserts that those studies were "skewed" and

---

[6] Nexium was approved at 20 mg for maintenance of healing of EE and for treatment of s-GERD in patients not suffering from EE. *Id.*

"slanted" because they compared different doses of the two drugs—that is, they compared Nexium 40 mg to Prilosec's maximum approved dosage of 20 mg for healing EE. *Id.* at 17, ¶ 11; *id.* at 17, ¶ 75. "To be fair and objective," the Complaint asserts, "AstraZeneca should have escalated the dose of Prilosec as well." *Id.* at 17, ¶ 75. By not doing so, respondents allegedly "misled" physicians "by the studies with unfair comparisons." *Id.* at 26, ¶ 104.

Petitioners rely on the views of an FDA medical officer who believed "there is no benefit" to increasing Nexium's dose from 20 mg to 40 mg for healing EE, and who thus recommended against approving Nexium at 40 mg for that indication. *Id.* at 18, ¶ 79. Even though FDA authoritatively rejected this recommendation and approved Nexium 40 mg for healing EE, the Complaint maintains that AstraZeneca deceptively marketed Nexium at 40 mg "despite there being no clinical reason to do so." *Id.* at 19, ¶ 80; see also *id.* at 61, ¶ 155(e) (alleging that AstraZeneca acted unlawfully by "suppressing and/or omitting that the recommended dose of Nexium was 20 mg").

In petitioners' view, the studies comparing Nexium and Prilosec show that Nexium is essentially the same as Prilosec and offers "no clinical improvements" or "any medical benefits not available from use of Prilosec." *Id.* at 4, ¶ 14. Petitioners thus allege that the "objective conclusion from these studies that should have been part of AstraZeneca's disclosures to doctors and the Class would have been to simply double the standard dose of Prilosec, allow generic competition," and forget about Nexium. *Id.* at 18, ¶ 77.

On this basis, petitioners challenge what they allege are unfounded claims of Nexium's "superiority"

over Prilosec in the marketing of Nexium. *E.g.*, Pet. 2, 9-11, 25-26. Petitioners took the opportunity to amend an earlier complaint after an initial motion to dismiss, and quoted four television ads and attached eleven print ads. Nevertheless, petitioners were unable to identify a single advertisement in which AstraZeneca expressly promoted Nexium as "superior" to Prilosec, let alone a factual comparative statement they could allege was false. See generally Supp. App. 28-54, ¶¶ 111-142). Only two of the television ads and five of the print ads use the word "Prilosec," and none expressly states that Nexium is more effective than Prilosec. Indeed, the Complaint alleges that "[b]y 2002, all references to Prilosec were deleted from Nexium television advertisements." *Id.* at 32, ¶ 122. In light of these facts, petitioners conceded in the court of appeals that "it is true that no print ad uses the ***word*** 'superior' when comparing Nexium and Prilosec." Pls.-Appellants' Reply Br. 2.

Instead, Petitioners attack virtually every aspect of every Nexium ad as conveying a misleading message of "superiority." According to the Complaint, this deceptive message arises from:

- AstraZeneca's "proudly introduc[ing]" Nexium, Supp. App. 38-43, ¶¶ 126-131; *id.* at 62-63, ¶ 155(o);
- the description of Nexium as "new," see, *e.g.*, *id.* at 2, ¶ 7; *id.* at 29-30, ¶¶ 114, 116-117;
- the description of the conditions for which Nexium is indicated, including that it is "possible" to relieve heartburn and heal erosions in the esophagus with Nexium, *id.* 28-29, ¶¶ 112-14; *id.* at 31-32, ¶¶ 118-21; *id.* at 44-45, ¶¶ 132-33;

- the color (purple) of the Nexium capsule, *id.*; and
- AstraZeneca's urging consumers to "talk to your doctor" about Nexium, *id.* at 29, ¶ 113; *id.* at 31, ¶¶ 119-20.

These promotional statements are, in petitioners' view, misleading claims of Nexium's "superiority" over Prilosec because they "fail to disclose that . . . AstraZeneca manufactures a far less expensive drug [Prilosec] that is equally as effective." *Id.* at 45-55, ¶¶ 131, 133, 135, 137, 139, 141, 143; see also *id.* at 29, ¶ 114 (attacking ad for "failing to mention that the exact same relief" is possible with Prilosec); *id.* at 32, ¶ 122 (alleging that AstraZeneca's DTC advertising after 2002 made "no mention of the fact [that] it also manufactured an equally effective drug"); *id.* at 39, ¶ 127 (calling it misleading to "'proudly introduce'" Nexium when Nexium is "simply the same basic drug with the same clinical benefits" as Prilosec).

The Complaint, on behalf of a putative nationwide class, alleges claims for violation of the Delaware Consumer Fraud Act ("DCFA"), Del. Code, tit. 6, § 2511, *et seq.*, violation of the consumer protection statutes of all 50 states, unjust enrichment, and negligent misrepresentation. The Complaint seeks relief including actual and punitive damages, restitution, and injunctive relief.

4. *The district court judgment.* The district court granted respondents' motion to dismiss. As relevant here, the district court agreed with respondents that petitioners' claims were preempted by the FDCA and FDA regulations.

The district court recognized that the "information included in the labeling of a new drug reflects a

determination by FDA that the information is not 'false or misleading.'" Pet. App. 52a, 57a. This determination created, in the district court's view, a safe harbor of protected marketing: "if the FDA labeling supports the statements made in advertising for an FDA-approved drug, the statements are not actionable." *Id.* at 52a. The court reviewed each allegedly false statement identified in the Complaint, and determined that each was truthful and supported by Nexium's FDA-approved labeling. *Id.* at 53a-56a. The court emphasized that it "did not find any explicit statements that Nexium was 'superior' to Prilosec" and further rejected Plaintiff's implied superiority claim based on the "consisten[cy]" between Nexium's labeling and the challenged marketing statements. *Id.* at 58a. In short, the district court dismissed petitioners' false advertising claims because the allegedly false and misleading statements were supported by Nexium's labeling.

5. *The court of appeals affirms.* The court of appeals agreed that federal law preempted petitioners' claims based on FDA's approval of Nexium and its labeling and the relationship between FDA labeling and advertising regulations.[7] From the outset, the court of appeals recognized that petitioners' claims depend on attacking the studies and drug comparison referenced in Nexium's

---

[7] The district court's review of Nexium's labeling, the challenged advertisements, and FDA's labeling and advertising regulations led it to dismiss petitioners' DCFA claim both under the DCFA "safe harbor" provision, Del. Code, tit. 6, § 2513(b)(2), and alternatively on preemption grounds. Pet. App. 56a-57a. The court of appeals disagreed as to the state law ground for dismissal because it construed the safe harbor narrowly to apply based only on FTC regulations, not FDA regulations. *Id.* at 6a, 16a.

labeling, with the Complaint asserting that AstraZeneca "incorrectly represented that Nexium was superior to Prilosec" because "a dose of 40 mg is not needed in most patients and that a fair comparison of 20 mg of Nexium to 20 mg of Prilosec would not have proven Nexium to be superior." Pet. App. 4a.

The court then reviewed FDA's extensive regulation of both prescription drug labeling and advertising. Pet. App. 12a-14a, 18a-21a. The court emphasized the "essential affinity between advertising and labeling" in the FDCA and FDA regulations, explaining that "the rules ... govern[ing] labeling also form the basis for the advertising regulations." *Id.* at 26-27a. The court also canvassed basic principles of conflict preemption. It observed that preemption may arise out of the "confluence between congressional purpose and agency purpose," *id.* at 24a, and where state law claims "frustrate regulations that have been promulgated following a specific inquiry into a particular area of agency authority," *id.* at 25a. The court thus recognized the potential for state law claims to "unnecessarily frustrate the FDCA's purpose and FDA regulations," given the "extensive and specific" agency involvement in prescription-drug advertising. *Id.* at 26a.

In light of these principles, and the nature of petitioners' claims, the court of appeals agreed that petitioners' claims are preempted. The court of appeals observed that the "strong[ ] case for preemption occurs when FDA-approved labeling is the basis for allegedly fraudulent representations made in prescription drug advertising." Pet. App. 26. This is so because "to the extent that the advertising statements regarding Nexium are consistent with statements used in the labeling approved by FDA,

FDA has determined they are not false or misleading." *Id.* at 13a. Moreover, "[a]lthough the FDA did not explicitly approve Zeneca's advertising, the FDA did approve Nexium's labeling, which included clinical studies that showed statistically significant healing rates for 40 mg of Nexium as compared to 20 mg of omeprazole." *Id.* at 20a n.9. Given that the court of appeals, like the district court, recognized that petitioners' claims were premised on their view that the studies and drug comparison included in Nexium's labeling were misleading; *id.* at 4a, 49a, 58a n.5, this is just such a "strong[ ] case," *id.* at 26a.

The court of appeals' extensive discussion of the labeling and advertising regulations led it to consider whether a complaint's claims "might be actionable" when they "are not supported by the labeling," but it ultimately recognized that "it need not decide this question now." Pet. App. 14a. The ultimate, operative principle in this case was straightforward: the purpose of the FDCA "would be frustrated if states were allowed to interpose consumer fraud laws that permitted plaintiffs to question the veracity of statements approved by FDA." *Id.* at 27a. That principle led the court of appeals to conclude that conflict preemption applied "in this setting" and to affirm the dismissal of "the plaintiffs' state consumer fraud claims." *Id.* at 28a.

Judge Cowen dissented. Because he viewed the labeling as insufficient to support the challenged advertising, he would not have found the claims preempted. See Pet. App. 35a-38a.

REASONS FOR DENYING THE PETITION

The premise of the petition is that the court of appeals held that *all* state law false advertising

claims involving prescription drugs are preempted. Pet. *i*, 2-3, 17, 23, 27, 30. This case does not present that issue. This is an ordinary conflict preemption case, and the conflict with federal law is stark. This putative nationwide class action alleges that introducing and marketing Nexium as an effective new PPI from the makers of Prilosec was inherently deceptive, that any promotion of Nexium necessarily conveyed a message of superiority, and that AstraZeneca's comparative testing of Nexium and Prilosec was skewed because it compared different doses of the two drugs. This lawsuit is irreconcilable with FDA's decision to approve Nexium as a new and effective drug, and to approve labeling that summarizes the results of the very studies comparing different doses of Nexium and Prilosec that petitioners attack as misleading. Petitioners' claims directly conflict with Congress's decision to give FDA exclusive authority to decide whether to approve a new drug for marketing, to determine what information goes on the labeling, and to make labeling the foundation of what a pharmaceutical company is permitted to use in promoting an approved drug. The Complaint cannot go forward without disrupting the detailed statutory and regulatory scheme that expressly permits advertising supported by labeling that FDA necessarily has found is neither false nor misleading in any particular. The dismissal of petitioners' claims is based on uncontroversial, indeed unchallenged, principles of conflict preemption.

The Third Circuit's decision nowhere mentions "field" preemption. Even reading the decision as petitioners do, this Court's review would remain unwarranted because no decision of any state high court or federal appellate court discusses federal

preemption of state false advertising claims by the federal scheme regulating prescription-drug labeling and advertising. There is thus no urgent need for this Court's review of this relatively unexplored issue. Instead, it would be prudent for this Court to allow other courts, including other panels in the Third Circuit, to give the decision below whatever effect they believe is appropriate as cases arise in the future before devoting resources to a legal issue that petitioners strain to present here. That would be especially prudent because the district court unambiguously concluded that all the challenged advertising was supported by the labeling. Pet. App. 53a-56a. If this Court were to agree, then it would not reach petitioners' issue because affirmance would remain appropriate on a narrow, undisputed, and controlling conflict preemption principle.

1. Conflict preemption precludes a state law false advertising claim that attacks statements supported by FDA-approved labeling. Such claims directly conflict with and obstruct the specific FDA regulations regarding labeling and advertising.

"[S]tate law is naturally preempted to the extent of any conflict with" federal law. *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). Conflict preemption arises "when compliance with both federal and state regulations is a physical impossibility, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hillsborough Cty.* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985) (internal quotation marks and citations omitted). "Federal regulations have no less pre-emptive effect than federal statutes. Where Congress has directed an administrator to exercise his discretion, his judgments are subject to judicial

review only to determine whether he has exceeded his statutory authority or acted arbitrarily." *Fidelity Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153-54 (1982).

These principles of conflict preemption might well have been developed with the role of FDA in regulating the labeling and advertising of prescription drugs in mind. Congress has made clear that FDA is the "expert agency," *Hynson*, 412 U.S. at 627, with exclusive authority over new drug approval. FDA reviews the labeling in deciding whether to approve that drug for marketing in the United States. See Pet. App. 11a-13a, 18a; *supra* at 3-4. FDA cannot approve a drug unless it reaches a substantive conclusion that the statements and information in the labeling are neither false nor misleading. See 21 U.S.C. § 355(d); Pet. App. 13a (citing, *inter alia*, 21 U.S.C. § 352(a); 21 C.F.R. § 314.125(b)(6)). Recognizing FDA's expertise, Congress placed FDA in charge of regulating prescription drug advertising. 21 U.S.C. § 352(n). Because labeling "also serves as the basis for product promotion," Professional Product Labeling, 60 Fed. Reg. at 52,196, FDA regulations permit a drug sponsor to advertise its drug pursuant to FDA-approved labeling. See Pet. App. 26a; *supra* at 6-7. The court of appeals thus aptly described the FDA regulatory structure as reflecting the "essential affinity between advertising and labeling." Pet. App. 26a.

As the court of appeals acknowledged, a "strong[] case for preemption" occurs where "FDA-approved labeling is the basis for allegedly fraudulent representations made in prescription drug advertising." Pet. App. 26a. State court plaintiffs may not "question the veracity of statements approved by FDA." *Id.* at 27a. State law claims that would

penalize drugmakers for disseminating information that FDA has concluded should be made public (in the labeling) and has concluded is not "false or misleading in any particular," 21 C.F.R. § 201.56(a)(2), would stand as an obstacle to Congress's purposes and the advancement of federal policy. Indeed, FDA itself has so concluded: "State law conflicts with and stands as an obstacle to achievement of the full objectives and purposes of Federal law if it purports to preclude a firm from including in labeling or advertising a statement that is included in prescription drug labeling." Labeling Rule, 71 Fed. Reg. at 3935-36.

2. Petitioners do not challenge these fundamental legal principles. Indeed, in the court of appeals, petitioners acknowledged that they could not "request that AstraZeneca alter any part of Nexium's labeling or *labeling-dependent statements in Nexium advertisements*." Pls.-Appellants' Opening Br. 34 (emphasis added). Instead, their petition positions the Complaint as not implicating the preemptive effect of FDA's approval of Nexium. But this litigation has, from the outset, been about whether the Complaint runs afoul of a preemption rule so basic that petitioners have, as a formal matter, not disputed it.

The district court carefully analyzed the allegations in the Complaint and concluded that none of the specific promotional statements attacked in the Complaint goes beyond the labeling. Pet. App. 53a-56a. That view is amply supported by the record, and this Court certainly does not sit to repeat such case-specific tasks. Were the Court to grant review, however, determining whether the judgment could be affirmed on that narrow ground would be the first inquiry.

That case-specific issue would be resolved as the district court resolved it. Although petitioners claim to be attacking the promotion of Nexium as "superior" to Prilosec, their Complaint shows otherwise. *Supra* at 10-11. The petition itself cites only ¶¶ 116-17 of the Complaint as exemplifying misleading DTC advertising. Pet. 11. This is the advertisement to which those paragraphs refer:

> Thinking about Nexium, today's purple pill? Good. But don't just think about Nexium, talk to your doctor about it. Find out if Nexium is right for you. Nexium – it's today's purple pill.

Supp. App. 29, ¶ 115.

Petitioners' reliance on this allegation lays bare why conflict preemption forecloses their claims. This advertisement makes no actual representations of fact and merely encourages further inquiry about Nexium. Petitioners are thus contending that even the most straightforward promotion of Nexium is inherently misleading because it contains – at best – an implicit comparison of Nexium to Prilosec. See Supp. App. 2, ¶7 ("[W]hy market a product as 'new' if it were not somehow better than the prior version?"). That claim cannot be reconciled with a federal scheme that specifically permits such advertising, based on labeling that expressly compares Nexium to Prilosec, and expressly summarizes studies on the relative efficacy of Nexium and Prilosec that supported approval of Nexium at a 40 mg dose for healing EE.

Similarly, where the petition and Complaint identify factual advertising statements, those statements are supported by the labeling. For example, it is not false or misleading to say that "relief is possible with the purple pill called Nexium,"

Pet. 11, because the labeling clearly indicates that Nexium was approved for relieving symptoms associated with GERD and EE. Similarly, it cannot be false or misleading to describe Nexium as a "new" drug,[8] to call it "powerful" for patients with EE,[9] or to promote Nexium's "healing rates" by showing doctors the studies featured in the FDA-approved labeling.[10] *Id.* at 9-10.[11]

Petitioners only underscore that they seek to challenge agency action in pointing to their proffer that "'in negotiations between FDA and AstraZeneca regarding Nexium labeling, FDA stated that it would not approve any representations by AstraZeneca that Nexium is more effective than Prilosec.'" Pet. 3

---

[8] FDA indisputably approved Nexium as a "new" PPI (Supp. App. at 2, ¶ 6) and FDA regulations expressly permit drugs to be promoted as "new" within six months of launch. FDA, DDMAC, *Frequently Asked Questions* (Nov. 7, 2006), *at* http://www.fda.gov/cder/ddmac/faqs.htm#new (FDA permits advertising drugs as "new" for six months after launch).

[9] 21 C.F.R. § 202.1(e)(3)(ii) (permitting promotion of drug efficacy based on single indication); Nexium Labeling at 10-11 (summarizing studies showing efficacy of Nexium in healing and resolving s-GERD for EE patients).

[10] Petitioners rely on a *Wall Street Journal* article as exemplifying deceptive detailing practices, but the article merely referred to showing the doctor "data comparing 40 mg. of Nexium to 20 mg. of Prilosec"—the very same data FDA considered and permitted for inclusion in the labeling. Supp. App. 17, ¶ 88.

[11] Petitioners have also attempted to rely, both in the district court and before this Court, on the language of the company's 2000 Annual Report. Pet. 9-10 (citing Compl. ¶ 89). There are no allegations, however, that the Annual Report—which was prepared prior to Nexium's approval by FDA—was ever used in marketing Nexium. The district court correctly disregarded statements in this report. Pet. App. 51a n.3.

(quoting Pet. App. 30a). This proffer is not different in kind from the Complaint's reliance on the medical reviewer's recommendation that the agency not approve a 40 mg dose of Nexium for healing EE because "'there is no benefit" to such a dose. Supp. App. 18, ¶ 79. FDA regulations make clear that pre-approval meetings and correspondence do "not constitute final administrative action." 21 C.F.R. § 10.65(a); see also *id.* § 10.85(k) (providing that statement "given by an FDA employee orally ... is an informal communication" that "does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed"). It is thus the labeling that reflects the "agency's formal, authoritative conclusions" arising out of the NDA process and provides the basis for product promotion. Labeling Rule, 71 Fed. Reg. at 3968; see also 21 C.F.R. § 202.1(e); Professional Product Labeling, 60 Fed. Reg. at 52,196.

The foregoing examples, though not exhaustive, suffice to show that petitioners do not really contest particular factual representations in advertising. Petitioners never identify any allegedly misleading aspect of the ads that would not be equally applicable to the labeling.

Rather, the complaint inherently challenges the federal statutory and regulatory scheme that granted FDA exclusive authority to review and approve the final labeling for Nexium, to permit promotion based on that labeling, to approve a 40 mg dose of Nexium for healing EE, and to rely upon comparative studies with Prilosec that petitioners believe are misleading. See Pet. App. 4a, 20a n.9; *id.* at 52a-56a. FDA expressly permits promotion based on studies summarized in labeling, and retains expansive power

to monitor and prevent false advertising. See 21 C.F.R. § 202.1(e)(3)(ii), (4), (6)(i); Labeling Rule, 71 Fed. Reg. at 3961; Professional Product Labeling, 60 Fed. Reg. at 52,196.[12] Petitioners nowhere allege that FDA issued warning letters against the Nexium promotion that referred to Prilosec. Their Complaint necessarily asks a jury, under the rubric of state law, to second-guess regulatory decisions (such as whether the comparative studies were "slanted" or "skewed") that federal law squarely commits to FDA. They have no plausible false advertising claim apart from their labeling-dependent challenge. *Cf. Bell Atl. Corp.* v. *Twombly*, 127 S. Ct. 1955, 1965-66 (2007) (explaining that, even under Rule 8, a complaint must provide "more than labels and conclusions," and "naked assertion[s]" that conduct was unlawful are insufficient to justify proceeding with expensive and burdensome class litigation).

3. The decision below does not conflict with any decision of this Court or any provision of the FDCA. Petitioners argue to the contrary only by ignoring the uncontroversial conflict preemption principle that supports dismissal of the Complaint. Instead, petitioners argue that the court of appeals held that all state false advertising claims involving prescription drugs are preempted, regardless of whether the challenged statements are supported by FDA-approved labeling, and that this is an error of

---

[12] See also FDA, *Guidance for Industry: Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products – Content and Format* 2 (Jan. 2006), *available at* http://www.fda.gov/CDER/GUIDANCE/5534fnl.pdf (clinical studies section of labeling describes "adequate and well-controlled" studies that provide "primary support for effectiveness" and "facilitate an understanding of how to use the drug safely and effectively").

exceptional importance, Pet. 2-3, 17, 23, 26-27. At best, petitioners' assertion that the court of appeals misapplied this Court's preemption decisions or misread the statute amounts to a call for error correction that this Court routinely rejects.

Under any reading, however, the decision below does not conflict with a decision of this Court. Petitioners' effort to create a conflict turns solely on the case-specific question whether their state law claims "are consistent with" the applicable federal regulations. Pet. 24. As discussed above, their claims are not "consistent with" the regulations; they directly conflict with the federal regulatory scheme.

The cases cited by petitioners, such as *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 869, 870 (2000), *Fidelity Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141 (1982), *Louisiana Public Service Commission* v. *FCC*, 476 U.S. 355 (1986), and *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), all support the court of appeals' decision, which is why the court relied upon those decisions. *Geier* is analogous here because this Court held that state law claims that would have made it unlawful to fail to install an airbag in an automobile are preempted by a federal agency's decision to permit manufacturers to phase airbags in over time. 529 U.S. at 864-65, 874-85. Here, state law claims that attack promoting Nexium based on its labeling are preempted by the agency's decision to permit such promotion. As in *Geier*, this case involves the attempt to enforce state standards where state laws would "frustrate regulations that have been promulgated following a specific inquiry into a particular area of agency authority." Pet. App. 24a-25a. *Fidelity Federal* and *Louisiana Public Service* also stand for the proposition that "agency regulations are also a source

of preemptive law." Pet. App. 23a-25a. And the court of appeals properly cited *Buckman* as an example of a case where preemption was appropriate to preserve agency "flexibility ... to pursue 'difficult (and often competing) objectives.'" *Id.* at 25a (quoting *Buckman*, 531 U.S. at 349). Likewise, the court of appeals determined, "plaintiffs' claims against Zeneca under state consumer fraud laws" would frustrate federal purposes. *Id.* 26a.[13]

Petitioners beg the question when they assert that the decision below conflicts with *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005). Contrary to petitioners' suggestion, the dismissal of their claims does not rest "solely on the extent of FDA regulations." Pet. 22. Preemption is appropriate here because their claims would require a state court to second-guess FDA's expert judgments reflected in

---

[13] Petitioners also argue in passing that the court's decision should be reviewed because 21 U.S.C. § 352(n) refers only to print or broadcast advertising and not oral representations by sales representatives. Pet. 21. In fact, the dismissal of the Complaint does not rest exclusively on § 352(n), but on the conflict between petitioners' claims and Nexium's labeling. In any event, FDA has asserted authority over oral representations. See, *e.g.*, Warning Letter to John C. Martin, Gilead Sciences, Inc. 1 (July 29, 2003), http://www.fda.gov/foi/warning_letters/archive/g4180d.pdf (issuing warning based on "oral representations made at Gilead's promotional exhibit booth"); *see also* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed Reg. 64,074, 64,075-76 (Dec. 3, 1997) (Congress intended broad construction of "advertisement" in FDCA, such that the terms includes information from drug sponsors (other than labeling) "intended to supplement or explain the product"). Because petitioners' allegations regarding oral representations are substantively no different from those attacking print and broadcast promotions, their oral misrepresentation claims are just as barred as their print misrepresentation claims.

Nexium's labeling. For the same reason, there is no conflict with *Hillsborough County*, which, like *Bates*, merely stands for the inapplicable proposition that extensive federal regulation, by itself, does not support field preemption. Pet. 22-23 (quoting 417 U.S. at 717-18). Further, *Hillsborough County* rejected conflict preemption in the context of that case because the putative obstacle to the accomplishment of federal objectives was deemed "speculative." 471 U.S. at 720. Here, for the reasons discussed above, the conflict between petitioners' claims and the federal regulatory scheme is not speculative, but clear, unavoidable, and at the heart of the case.

Petitioners' reliance on Section 202 of the Drug Amendments of 1962 is similarly unavailing. That provision states that the amendments shall not invalidate a provision of state law "unless there is a direct and positive conflict between such amendments and such provision of State law." Pub. L. No. 87-781, § 202, 76 Stat. 780, 793. Neither party cited Section 202 below. Its meaning is not at issue because respondents have always maintained that, under ordinary preemption principles, there is a conflict between petitioners' claims and federal law. A savings clause such as section 202 does "not *bar* the ordinary working of conflict pre-emption principles" and does "not foreclose ... the possibility that a federal [regulatory] standard will pre-empt a state common-law tort action." *Geier*, 529 U.S. at 869, 870. Certainly nothing in Section 202 would bar a finding of preemption when FDA-approved labeling is the basis of challenged advertising statements.[14]

---

[14] Petitioners also criticize the court of appeals' reference to 21 U.S.C. § 337(a), which provides that "all ... proceedings for the

4. The decision below also does not conflict with any decision of a federal court of appeals or state court of last resort. First, petitioners do not suggest there is any conflict with the narrow ground for dismissing the Complaint—that all promotions they attack are supported by Nexium's FDA-approved labeling. Second, even construing the decision below broadly as petitioners do, petitioners cite to no appellate decision even discussing the "field" preemption of prescription-drug false advertising claims or the scope of preemption arising out of the "essential affinity" between FDA's labeling and advertising regulations. Pet. App. 26a.

In this respect, the case law regarding the preemption of prescription-drug false advertising claims stands in sharp contrast to that involving the preemption of prescription-drug failure-to-warn claims. Numerous courts have addressed failure-to-warn claims, but petitioners cite none addressing the scope of preemption of prescription-drug false advertising claims and few courts (and no other circuit courts) have addressed the issue. Moreover, no court has considered the scope of advertising

---

enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." *See* Pet. 25. But the decision in no way rested upon that provision, which merely supports the broader, applicable point that the federal scheme provides FDA with extensive authority and discretion in enforcing the FDCA and, specifically, in ensuring a proper balance in the dissemination of information about prescription drugs. Pet. App. 28a; *cf.* 21 U.S.C. § 336 (providing that nothing in FDCA "shall be construed as requiring the Secretary to report for prosecution ... minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning"); 21 C.F.R. § 10.30 (allowing citizens to report alleged violations and to petition the agency to take regulatory or enforcement action).

preemption in light of the recent amendments to the FDCA. Given the dearth of consideration of the issue in the lower courts, as well as the uncertain impact of new legislation, plenary review now of the issue petitioners seek to present would at best be premature.

The relative paucity of case law on preemption in the advertising context also reflects the desire of state legislatures not to have consumer fraud laws invade this sphere of federal authority. Broad challenges to the promotion of prescription drugs have been rejected on state law grounds under various "safe harbor" provisions to state consumer fraud laws. Although the court of appeals construed Delaware's safe harbor narrowly as covering only conduct governed by FTC, not FDA, regulations (Pet. App. 15a-16a; *supra* note 7), the safe harbor provisions in other states are broader than Delaware's. For example, the Florida Deceptive and Unfair Trade Practices Act broadly exempts from its application any "act or practice required or specifically permitted by federal or state law." Fla. Stat. § 501.212(1). Such provisions have repeatedly provided an independent state law ground for dismissing claims either identical or comparable to those here.[15] For this reason as well, the issue on

---

[15] Florida courts have rejected a virtually identical challenge to the advertising of Nexium under that state's safe harbor, on the ground that all of the challenged promotional statements were supported by Nexium's FDA-approved labeling, as well as on the preemption grounds discussed here. *Prohias* v. *AstraZeneca Pharms., L.P.*, 958 So. 2d 1054, 1056 (Fla. Dist. Ct. App.), *review denied*, 969 So. 2d 1014 (Fla. Nov. 7, 2007) (table). Likewise, the consumer protection law of Illinois contains a safe harbor that has been interpreted to bar a challenge to promotional statements comparing different dosages of two drugs that, even if not directly approved by FDA, are

which petitioners seek review is unlikely to recur with the frequency that would warrant this Court's review.

Petitioners rely on *Levine* v. *Wyeth*, --- A.2d ---, 2006 WL 3041078 (Vt. Oct. 27, 2006), which this Court has agreed to review. *Wyeth* v. *Levine*, 75 U.S.L.W. 3500, 76 U.S.L.W. 3391 (Jan. 18, 2008) (No. 06-1249). *Levine* is irrelevant to the field-preemption gloss that petitioners place on the decision below, because the manufacturer in *Levine* "concede[dly]" did not argue for field preemption. *Levine*, 2006 WL 3041078, ¶ 8. As shown below, *Levine* also is in accord with the principle of conflict preemption that is dispositive here. Perhaps for that reason, petitioners did not cite *Levine* below, either pursuant to Fed. R. App. P. 28(j), or in their petition for rehearing en banc.

Levine involves claims about inadequate safety warnings, not false advertising claims. The distinction is significant because the Vermont court's decision turned on its interpretation of a particular regulation applicable to product safety warnings. According to the Vermont Supreme Court, the "Changes Being Effected" ("CBE") regulation, 21 C.F.R. § 314.70(c), permitted Wyeth to change its labeling unilaterally to "'strengthen a ... warning'" or an "'instruction'" for "'safe use,'" thus leaving "leeway" for state law to determine whether Wyeth, in fact, should have changed its labeling. *Levine*, 2006

"sufficiently within what is authorized by federal law." *Bober* v. *Glaxo Wellcome PLC*, 246 F.3d 934, 941 (7th Cir. 2001); see also *N.J. Citizen Action* v. *Schering-Plough Corp.*, 842 A.2d 174, 177 (N.J. Super. Ct. App. Div. 2003) (dismissing broad challenge to allegedly false, implicit message of efficacy in all Claritin advertising based on "compliance with FDA regulations including regulations relating to DTC marketing campaigns").

WL 3041078, ¶¶ 12-14 (quoting § 314.70(c)); see also *id.* ¶ 22 (no conflict because "defendant was free under ¶ 314.70(c) to strengthen the warning without prior FDA approval"). Though crucial to the decision in *Levine*, the CBE regulation is inapplicable here, because petitioners brought only false advertising claims involving drug efficacy, and did not challenge the safety warnings in the labeling.

The Vermont Supreme Court also accepted the principle that state law may not be used to second-guess FDA's expert judgment; it rejected conflict preemption because it concluded that FDA never addressed the warning at issue. *Levine*, 2006 WL 3041078, ¶ 23. Here, by contrast, petitioners attack precisely what the labeling shows FDA did approve as the basis for the promotion of Nexium, namely, the results of comparative efficacy studies of different dosages of Nexium and Prilosec, and a 40 mg dose of Nexium for healing EE. Because the core principle of conflict preemption that is dispositive here was accepted in *Levine*, *id.*, and because the CBE regulation is inapplicable here, *Levine* provides no basis to grant or hold the petition.[16]

The decision below also does not conflict with *Perez* v. *Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. 1999). *Perez* addresses state law standards for duty-to-warn claims, principally focusing on whether the learned intermediary doctrine applied to DTC

---

[16] The same is true of the other FDA-preemption case pending before the Court. *Warner-Lambert Co.* v. *Kent*, No. 06-1498 (set for argument Feb. 25, 2008), involves federal preemption of state law claims that depend on challenges to the adequacy of disclosures to FDA during the drug approval process; in the district court, petitioners disavowed any claim that AstraZeneca committed a fraud on FDA in obtaining approval for Nexium.

advertising as a matter of state law. See *id.* at 1246-47. It nowhere discusses preemption.

The other lower court decisions cited over the final pages of the petition reflect more of the same. Petitioners cite numerous cases for the proposition that no court has found the preemption of *all* prescription-drug false advertising claims. See Pet. 30-31. Not only is that not the operative principle of the decision below, but the cited cases do not address the question as petitioners frame it. Indeed, petitioners cite no case that considers, let alone attempts to define, the furthest boundaries of conflict preemption in the area of prescription drug advertising, other than the decision below (as petitioners read it).[17] Petitioners' reliance on various cases interpreting the phrase "direct and positive conflict" in different statutory schemes, Pet. 32-34, is also inapposite because the meaning of the phrase "direct and positive conflict" in § 202 of the 1962 Drug Amendments is not at issue, much less the meaning of that phrase in other statutes.

There is ample support for the dismissal of petitioners' claims on the undisputed preemption principle that petitioners may not challenge labeling-dependent statements in Nexium advertising.

---

[17] Indeed, certain of the cases actually confirm the primacy of FDA's labeling decisions by emphasizing that the claims challenged advertising *contrary* to FDA-approved labels. *In re Warfarin Sodium Antitrust Litg.*, 391 F.3d 516, 521-23 (3d Cir. 2004) (claim that defendant falsely promoted its brand-name drug as superior to the generic version, which FDA had approved as therapeutically equivalent); *Alpharma, Inc.* v. *Pennfield Oil Co.*, 411 F.3d 934, 939-40 (8th Cir. 2005) (Lanham Act claims alleging that the defendant advertised its animal feed as having an approved use that FDA had not in fact approved).

Preemption has arisen infrequently in this context; should it arise in the future, other courts need not read the court of appeals' decision as broadly as petitioners do. The availability of a narrow, straightforward basis of affirmance would inhibit this Court's ability even to consider the field-preemption rule petitioners ascribe to the opinion below. Review in this case would be as imprudent as it is unwarranted.

CONCLUSION

The petition for writ of certiorari should be denied.

Respectfully submitted,

JACK B. BLUMENFELD
R. JUDSON SCAGGS, JR.
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 North Market Street
P. O. Box 1347
Wilmington, DE 19899
(302) 658-9200

MARK E. HADDAD*
DAVID R. CARPENTER
SIDLEY AUSTIN LLP
555 West Fifth Street, Suite 4000
Los Angeles, CA 90013
(213) 896-6000

ROBERT N. HOCHMAN
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, Illinois 60603
(312) 853-7036

Counsel for Respondents

February 21, 2008

* Counsel of Record

87

(3)

No. 07-822

FILED
MAR 4 - 2008
OFFICE OF THE CLERK
SUPREME COURT, U.S.

IN THE

Supreme Court of the United States

PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, JOSEPH MACKEN, COMMISSIONER LINDA A. WATTERS, AFSCME DISTRICT COUNCIL 47 HEALTH &WELFARE FUND, VICTORIA SCOFIELD, JANET MCGRORTY, RICHARD TIKKURI, WISCONSIN CITIZEN ACTION, UNITED SENIOR ACTION OF INDIANA, NORTH CAROLINA FAIR SHARE,

Petitioners,

v.

ZENECA, INC. and ASTRAZENECA PHARMACEUTICALS, L.P.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

REPLY BRIEF

STEVE W. BERMAN
Counsel of Record
CRAIG R. SPIEGEL
HAGENS BERMAN SOBOL SHAPIRO LLP
1301 Fifth Ave., Suite 2900
Seattle, Washington 98101
(206) 623-7292

Attorneys for Petitioners

(Additional Counsel Listed on Inside Cover)

214467

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

Barbara J. Hart
Christopher J. McDonald
Labaton Sucharow LLP
140 Broadway
New York, NY 10005
(212) 907-0700

James R. Malone, Jr.
Michael D. Gottsch
Daniel B. Scott
Timothy N. Mathews
Chimicles & Tikellis LLP
361 W. Lancaster Avenue
Haverford, PA 19041
(610) 642-8500

Ellen Meriwether
Bryan L. Clobes
Cafferty Faucher LLP
1717 Arch Street
Suite 3610
Philadelphia, PA 19103
(215) 864-2800

Robert S. Schachter
Joseph Lipofsky
Paul Kleidman
Zwerling, Schachter
& Zwerling, LLP
41 Madison Avenue,
32nd Floor
New York, NY 10010
(212) 223-3900

Ronald S. Goldser
Zimmerman Reed, PLLP
651 Nicollet Mall, Suite 501
Minneapolis, MN 55402
(612) 341-0400

Jeffrey S. Goddess
Rosenthal Monhait &
Goddess, P.A.
919 Market Street, Suite 1401
Wilmington, DE 19801
(302) 656-4433

Jeffrey L. Kodroff
Theodore M. Lieverman
Spector, Roseman &
Kodroff, P.C.
1818 Market Street
Suite 2500
Philadelphia, PA 19103
(215) 496-0300

Pamela S. Tikellis
A. Zachary Naylor
Chimicles & Tikellis LLP
One Rodney Square
P.O. Box 1035
Wilmington, DE 19899
(302) 656-2500

L. Kendall Satterfield
Richard M. Volin
Finkelstein Thompson LLP
1050 30th Street, N.W.
Washington, D.C. 20007
(202) 337-8000

Richard Kirschner
Kirschner & Gartrell, P.C.
4910 Massachusetts Ave., NW
Suite 215
Washington, D.C. 20016
(202) 775-0087

Jason J. Thompson
Charfoos & Christensen, P.C.
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

CORPORATE DISCLOSURE STATEMENT

Petitioner's corporate disclosure statement was set forth at page *ii* of its Petition for a Writ of Certiorari, and there are no amendments to that statement.

TABLE OF CONTENTS

	Page
CORPORATE DISCLOSURE STATEMENT .	i
TABLE OF CONTENTS	ii
TABLE OF CITED AUTHORITIES	iv
ARGUMENT	1
I. THE THIRD CIRCUIT REJECTED RESPONDENTS' ARGUMENT THAT PETITIONERS' CLAIMS CONFLICT WITH THE FDA'S APPROVAL OF THE NEXIUM LABEL AND HELD THAT 21 U.S.C. §§ 337 AND 352(n) PREEMPT ALL STATE-LAW CLAIMS FOR DECEPTIVE ADVERTISING OF PRESCRIPTION DRUGS	2
II. THIS COURT SHOULD REVIEW THE HOLDING THAT THE FDCA PREEMPTS ALL STATE-LAW CLAIMS FOR DECEPTIVE ADVERTISING OF PRESCRIPTION DRUGS	5
III. THERE IS NO REASON FOR THIS COURT TO REVIEW THE THIRD CIRCUIT'S DECISION THAT PETITIONERS' CLAIMS ARE	

Contents

Page

CONSISTENT WITH THE FDA'S APPROVAL OF THE NEXIUM LABEL OR TO ADDRESS ANY OF THE OTHER CASE-SPECIFIC ARGUMENTS RAISED BY RESPONDENTS 8

CONCLUSION 9

TABLE OF CITED AUTHORITIES

Page

FEDERAL CASES

Riegel v. Medtronic, Inc.,
__ U.S. __, 2008 U.S. Lexis 2013 (Feb. 20, 2008) 7

STATE CASES

Farm Raised Salmon Cases,
__ Cal. 4th __, 2008 Cal. Lexis 1413
(Feb. 11, 2008) 7, 8

Levine v. Wyeth,
2006 Vt. 107 (2006) 6

Perez v. Wyeth Labs., Inc.,
161 N.J. 1, 734 A.2d 1245 (1999) 6-7

FEDERAL STATUTES

21 U.S.C. § 337 ..... *passim*

21 U.S.C. § 352(n) ..... *passim*

21 U.S.C. § 360k 7

P.L. 87-781 § 202, 76 Stat. 793 (Oct. 10, 1962) ... 6

ARGUMENT

In their *Brief in Opposition* ("Oppo."), Respondents incorrectly assert that this case presents case-specific issues that this Court should not review. To the contrary, this case presents the sweeping issue of whether 21 U.S.C. §§ 337 and 352(n) bar all state-law claims for deceptive advertising of prescription drugs, even if the claims are wholly consistent with the FDCA, with FDA regulations, with FDA findings, and with the approved label. Contrary to Respondents' argument, the majority based its preemption ruling on a broad interpretation of sections 337 and 352(n) that all such claims are preempted, and specifically rejected Respondents' argument that Petitioners' claims conflict with the Nexium label or with FDA regulations. The Third Circuit's ruling would apply to all claims for deceptive advertising of prescription drugs, eliminating the issue of whether a claim conflicts with or is consistent with the prescription drug's label. The ruling is in direct conflict with recent decisions of this Court and the highest courts of certain states. That ruling merits review by this Court.

I. THE THIRD CIRCUIT REJECTED RESPONDENTS' ARGUMENT THAT PETITIONERS' CLAIMS CONFLICT WITH THE FDA'S APPROVAL OF THE NEXIUM LABEL AND HELD THAT 21 U.S.C. §§ 337 AND 352(n) PREEMPT ALL STATE-LAW CLAIMS FOR DECEPTIVE ADVERTISING OF PRESCRIPTION DRUGS

The majority in the Third Circuit rejected Respondents' argument that Petitioners' claims conflict with the Nexium label, and instead held that all state-law claims for advertising prescription drugs are preempted by the FDCA and its enabling regulations. The majority first rejected Respondents' case-specific argument, stating:

> To the extent that the complaint alleges that Zeneca marketed Nexium as superior to Prilosec, those claims of superiority might be actionable inasmuch as such comparisons are not supported by the labeling and therefore might be false or misleading.

499 F.3d at 246.

The Court then plainly held that Petitioners' claims are preempted solely because all state-law claims for deceptive advertising of prescription drugs are preempted, regardless of whether there is a conflict

between the state-law claim and the FDCA, FDA regulations, FDA findings or the label at issue. The majority stated:

> Implied conflict preemption of state consumer fraud laws is required in this setting because both the FDCA and FDA regulations provide specific requirements for prescription drug advertising. Congress specifically determined that "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The high level of specificity in federal law and regulations with respect to prescription drug advertising is irreconcilable with general state laws that purport to govern all types of advertising. *See, e.g.*, 21 U.S.C. § 352(n); 21 C.F.R. § 314.81(b)(3). Accordingly, the plaintiffs' state consumer fraud claims are preempted.

Id. at 251-52.

The majority reaffirmed that holding when it held that Petitioners' claims are preempted even if the FDA explicitly told Respondents that they were not permitted to market Nexium as superior to Prilosec:

> Additionally, although the plaintiffs suggest that some additional facts might be pled in order to cure the defects of the complaint, amendment would be futile. In particular, the plaintiffs state that they

> could allege that "in negotiations between the FDA and AstraZeneca regarding Nexium labeling, the FDA stated it would not approve any representations by AstraZeneca that Nexium is more effective than Prilosec, and AstraZeneca responded it would not make any such statement." This will not overcome the deficiencies in the complaint because the advertisements are not subject to state consumer fraud law, as explained in part III.

499 F.3d at 252-53.

In the concluding section of its opinion, the majority reiterated the sweeping nature of its decision:

> By specifically excluding advertisements covered by 21 U.S.C. § 352(n) and the regulations promulgated thereunder from the scope of 15 U.S.C. § 52, Congress signaled its intent to give the FDA exclusive authority to regulate prescription drug advertising. The FDA has established specific regulations regarding such advertising. To allow generalized state consumer fraud laws to dictate the parameters of false and misleading advertising in the prescription drug context would pose an undue obstacle to both Congress's and the FDA's objectives in protecting the nation's prescription drug users. Accordingly, the state consumer fraud laws are preempted by the extensive federal legislative and regulatory framework.

499 F.3d at 253. Finally, in dissent, Judge Cowen

explained that the majority held that "the FDCA and the implementing regulations displace the Delaware Consumer Fraud Act and the consumer protection statutes of the fifty states." 499 F.3d at 254.

Thus, contrary to Respondents' arguments, the Third Circuit rejected Respondents' case-specific assertion that Petitioners' claims conflict with the FDA's approval of the Nexium label, and instead held that the FDCA preempts ***all*** state-law claims for deceptive advertising of prescription drugs.

II. THIS COURT SHOULD REVIEW THE HOLDING THAT THE FDCA PREEMPTS ALL STATE-LAW CLAIMS FOR DECEPTIVE ADVERTISING OF PRESCRIPTION DRUGS

The Third Circuit's holding that 21 U.S.C. §§ 337 and 352(n) bar all state-law claims for deceptive advertising of prescription drugs conflicts with decisions by this Court, by state courts of last resort and by federal appellate courts, as explained in the Petition. Respondents' arguments to the contrary are unavailing, because they rest on the incorrect premise that the majority of the Third Circuit panel held that Petitioners' claims are preempted because of a conflict with Nexium's label.

For example, Respondents incorrectly assert that the meaning of Section 202 of the Drug Amendments of 1962 "is not at issue because respondents have always maintained that, under ordinary preemption principles, there is a conflict between petitioners' claims and federal law." Oppo. at 25. The issue is not what Respondents

may have ***maintained*** but rather what the Third Circuit held. And, as discussed in the Petition and above, the majority did not agree with Respondents' contention that "ordinary preemption principles" bar Petitioners' claims. *See* 499 F.3d at 246 ("To the extent that the complaint alleges that Zeneca marketed Nexium as superior to Prilosec, those claims of superiority might be actionable inasmuch as such comparisons are not supported by the labeling and therefore might be false or misleading."). Instead, the majority held that section 352(n) bars ***all*** state-law claims for deceptive advertising of prescription drugs, even though section 202 of the Drug Amendments of 1962, which created section 21 U.S.C. § 352(n), states that "[n]othing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." P.L. 87-781 § 202, 76 Stat. 793 (Oct. 10, 1962). Therefore, contrary to Respondents' argument, section 202 of the Drug Amendments Act of 1962 is plainly at issue in this matter.

For the same reasons, cases interpreting section 202 of the Drug Amendments Act of 1962 and 21 U.S.C. § 352(n) as requiring an actual conflict with state law in order for preemption to apply are plainly relevant. For example, in *Levine v. Wyeth*, 2006 Vt. 107 (2006), *review granted*, __ U.S. __, 169 L. Ed. 2d 845 (Jan. 18, 2008), the Court held that Section 202 means that "Congress intended that the FDCA would leave state law in place except where it created a 'direct and positive conflict' between state and federal law." *Id.* at ¶ 27. Similarly, in *Perez v. Wyeth Labs. Inc.*, 161 N.J. 1, 734 A.2d 1245

(1999), the Court held that under section 352(n), compliance with FDA regulations relating to the advertisement of prescription drugs creates a rebuttable presumption of legality but rejected the argument that section 352(n) preempts all state-law claims for deceptive advertising or prescription drugs.

In addition, the majority's reliance on 21 U.S.C. § 337 in holding that Petitioners' claims are preempted, *see* 499 F.3d at 251-52, conflicts with numerous decisions by this Court, as explained in the Petition. Most recently, this Court held in *Riegel v. Medtronic, Inc.*, __ U.S. __, 2008 U.S. Lexis 2013, at *5 (Feb. 20, 2008), that "the pre-emption clause enacted in the Medical Device Amendments of 1976, 21 U.S.C. § 360k, bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the Food and Drug Administration (FDA)." This Court, however, explained that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at *30. In contrast, the Third Circuit majority held that sections 337 and 352(n) bar ***all*** state-law claims for deceptive advertising of prescription drugs, regardless of whether the claim parallels or instead conflicts with FDA regulations or findings.

The majority's reliance on section 337 also conflicts with a recent decision by the California Supreme Court. In *Farm Raised Salmon Cases*, __ Cal. 4th __, 2008 Cal. Lexis 1413, at *3 (Feb. 11, 2008), the Court held that section 337 does not preempt claims that "grocery stores violated state law by selling artificially colored farmed

salmon without disclosing to their customers the use of color additives." The Court explained that Section 337 does not apply to the state law claims presented here. "The statute, by its very terms, only implicates efforts to enforce *federal* law. What section 337 does *not* do is limit, prohibit, or affect private claims predicated on *state* laws." __ Cal. 4th at __, 2008 Cal. Lexis 1413, at *35 (emphasis in original). In contrast, the Third Circuit majority held that section 337 bars Petitioners' state-law claims in this matter, even though Petitioners do not seek to enforce federal law.

For all these reasons, and for the reasons stated in the Petition, the decision by the Third Circuit conflicts with decisions by this Court, by state courts of last resort and by federal appellate courts

III. THERE IS NO REASON FOR THIS COURT TO REVIEW THE THIRD CIRCUIT'S DECISION THAT PETITIONERS' CLAIMS ARE CONSISTENT WITH THE FDA'S APPROVAL OF THE NEXIUM LABEL OR TO ADDRESS ANY OF THE OTHER CASE-SPECIFIC ARGUMENTS RAISED BY RESPONDENTS

Respondents erroneously argue that regardless of the Third Circuit's sweeping holding, the Petition should be denied because the Third Circuit should have adopted a number of case-specific arguments proffered by Respondents. There is no reason for this Court to address Respondents' case-specific arguments and to decide whether the Third Circuit erred by not adopting those arguments. If this Court were to reverse the Third Circuit's sweeping decision that sections 337 and 352(n)

preempt all state-law claims for deceptive advertising of prescription drugs, the lower courts could then decide whether to address Respondents' case-specific arguments. The only issue that merits this Court's attention is the broad preemption holding, which has implications far beyond the confines of the particular dispute between Petitioners and Respondents.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

STEVE W. BERMAN
Counsel of Record
CRAIG R. SPIEGEL
HAGENS BERMAN SOBOL SHAPIRO LLP
1301 Fifth Ave., Suite 2900
Seattle, Washington 98101
(206) 623-7292

Attorneys for Petitioners

(Additional Counsel listed on inside cover)